UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

GILEAD SCIENCES, INC.,

Plaintiff and Counterdefendant,

v.

MERCK & CO., INC. (Defendant only), MERCK SHARP & DOHME CORP. and ISIS PHARMACEUTICALS, INC.,

Defendants and Counterclaimants.

Case No. 5:13-cv-04057-BLF

Ctrm: 3, 5th Floor
Judge: Honorable Beth Labson Freeman

OPENING EXPERT REPORT OF LESLIE Z. BENET, PH.D.

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I. Introduction

1. I, Leslie Z. Benet, have been retained by counsel for defendants Merck & Co, Inc., Merck Sharp & Dohme Corp. and Isis Pharmaceuticals, Inc. to compare certain claims of U.S. Patent Nos. 7,105,499 ("the '499 patent") and 8,481,712 ("the '712 patent") (collectively, the "Asserted Patents") to plaintiff Gilead Sciences, Inc.'s SOVALDI and HARVONI products and their use in accordance with the directions stated in their package inserts. Based on my analysis and investigation, I have reached certain conclusions and developed certain opinions on the issues that I discuss in this report. I expect to be available for deposition and to testify at trial.

II. Qualifications

2. My background and qualifications are more fully set out in my curriculum vitae, attached as Exhibit A. The following is a brief summary of my background and qualifications.

3. I am currently a Professor of Bioengineering and Therapeutic Sciences, Schools of Pharmacy and Medicine, at the University of California, San Francisco ("UCSF"). I am also a Co-Director for the Drug Studies Unit at UCSF.

4. I received my Bachelor of Arts in English in 1959 and my Bachelor of Science in Pharmacy in 1960 from the University of Michigan. In 1962, I received a Master's Degree in Pharmaceutical Chemistry, also from the University of Michigan. Three years later, in 1965, I was awarded a doctorate from UCSF in Pharmaceutical Chemistry. Since obtaining that degree, I have received eight honorary doctorate degrees, four from European universities and four from US institutions, the last in December, 2011 from the University of Michigan. I held a licentiate in

Pharmacy and am a credentialed Applied Pharmacologist with the American Board of Clinical Pharmacology.

5. In 1965, I joined the faculty of the School of Pharmacy at Washington State University, in Pullman, Washington. In 1969, I joined the Departments of Pharmacy and Pharmaceutical Chemistry within the School of Pharmacy at UCSF as an Assistant Professor. From 1969 to 1976, I progressed first from Assistant Professor to Associate Professor, and then to Professor. I served as Chairman of the Department of Biopharmaceutical Sciences at UCSF from 1978-1998.

6. My areas of specialization over the course of my career include pharmacokinetics/pharmacodynamics, biopharmaceutics, drug delivery and dosage forms, drug metabolism, drug transporters, bioequivalence and other scientific aspects of drug regulatory issues.

7. In addition to my teaching responsibilities, I have held leadership positions in a number of organizations in my field of study, including:

a. From 1985 to 1986, I served as President of the Academy of Pharmaceutical Research and Science (formerly the Academy of Pharmaceutical Sciences).

b. In 1986, I founded and served as the first President of the American Association of Pharmaceutical Scientists (AAPS). From 1986 to 1993, I variously held the positions of Treasurer, Member, and Chair of the Board of Directors of AAPS.

c. From 1988 to 2004, I served as a Specialist Member, Chairman, Past Chair, and Member of the Executive Committee of the Board of Pharmaceutical Sciences for the International Pharmaceutical Federation (FIP). From 2008 through 2012, I served as Chair of the FIP Foundation for Education and Research.

d. From 1992 to 1995 I served as a Member, President, and Chair of the Board of Directors of the American Association of Colleges of Pharmacy (AACP).

8. I have been awarded numerous awards, prizes and honors for work I have conducted in my field, including:

a. In 1982, I received the American Pharmacists Association (APhA) Academy of Pharmaceutical Sciences Research Achievement Award in Pharmaceutics and the University of Michigan, College of Pharmacy Distinguished Alumnus Award.

b. In 1987, I was elected to membership in the Institute of Medicine (IOM) of the U.S. National Academy of Sciences.

c. In 1988, I received the Distinguished Service Award of the American College of Clinical Pharmacology (ACCP), and in 1989 I was chosen to receive the first AAPS Distinguished Pharmaceutical Scientist Award.

d. In 1990, I was the recipient of the Rho Chi Lecture Award, and the UCSF School of Pharmacy Long Teaching Award.

e. In 1991, I received the AACP Volwiler Research Achievement Award.

f. In 1995, I received the Rawls-Palmer Progress in Medicine Award of the American Society of Clinical Pharmacology and Therapeutics (ASCPT) and delivered the American College of Clinical Pharmacy "Therapeutic Frontiers Lecture."

g. In 1996, I received the AAPS Distinguished Service Award, and in 2000 the APhA Takeru Higuchi Research Prize and the AAPS Wurster Research Award in Pharmaceutics.

h. In 2001, I was awarded the FIP Host-Madsen Medal and the UCSF Outstanding Faculty Mentorship Award.

i. In 2003, I was listed as one of the most highly cited pharmacologists worldwide, and continue to maintain that distinction, with my published peer reviewed publications having been cited more than 22,000 times.

j. In 2004, I was awarded the Pharmaceutical Sciences World Congress Research Achievement Award and the Controlled Release Society's Career Achievement in Oral Drug Delivery Award.

k. In 2007, I was selected as the Distinguished Clinical Research Lecturer at UCSF and made an International Honorary Member of the Japan Society for the Study of Xenobiotics.

l. In 2008, I was selected for the Nagai Foundation Tokyo Distinguished Lectureship.

m. In 2010, I was selected to receive the ASCPT Oscar B. Hunter Memorial Award in Therapeutics and in 2011, the ACCP Distinguished Investigator Award.

n. In 2012, I was made an Honorary Member of FIP.

o. In 2012, the September issue of *Pharmaceutical Research* was dedicated in my honor under the title "50 Years of Scientific Excellence and Still Going Strong" and in 2013, the September issue of the *Journal of Pharmaceutical Sciences* was dedicated in my honor under the title "Perspectives on a Pharmacokinetics Legend."

p. In 2013 I received the APhA Ebert prize for what was viewed as the most outstanding publication appearing in the *Journal of Pharmaceutical Sciences* during the previous

year, and the *AAPS Journal* Outstanding Manuscript Award for the same recognition in that journal.

q. In 2014, I was listed by Thompson Reuters as one of the most highly cited pharmacologists worldwide, and one of only 12 pharmacologists that were so listed in the 2001 and 2014 compilations.

9. I have published more than 540 articles, 7 books, and been granted 12 patents in the areas of pharmacokinetics, biopharmaceutics, drug delivery and pharmacodynamics. My published peer reviewed publications have been cited on more than 22,500 occasions in the scientific literature. My most recent work addresses the cooperative effects of metabolic enzymes of Cytochromes P-450 and transport proteins as related to the oral bioavailability and hepatic elimination of drugs. My most highly cited recent paper was my 2005 work describing a Biopharmaceutics Drug Disposition Classification System in which I proposed methodologies for predicting drug absorption and disposition, as well as drug-drug interactions, for all therapeutic drug agents.

10. Based on my expertise in the field of pharmacology, pharmacokinetics, drug delivery and drug metabolism, I have been invited to serve (and currently serve) on the editorial boards of several journals, including *Pharmacology* (1978 to present), *The AAPS Journal* (1999 to present), *Chemistry and Pharmaceutical Bulletin* (2000 to present), *Expert Opinion on Drug Metabolism and Toxicology* (2004-present) and *Archives of Drug Information* (2007-present). Selection to the editorial boards of these journals is based upon recognition by the scientific community that the individual is an established leader in the field of pharmacology, pharmacokinetics, drug delivery and drug metabolism. As a member of these editorial boards, I have reviewed, evaluated, and selected articles for publication based upon scientific merit in the

general area of pharmacology, pharmacokinetics, drug delivery and drug metabolism. In addition to my roles on the above-mentioned editorial boards, I was a Founder and Editor of the *Journal of Pharmacokinetics and Biopharmaceutics* (1973 to 1998) and served as the Associate Editor for *Pharmacology and Therapeutics* (1995 to 2000).

11. I served as Chair of the Pharmacology Study Section and the Pharmacological Sciences Review Committee for the NIH, the FDA CBER Peer Review Committee, the FDA Expert Panel on Individual Bioequivalence, the Board of Pharmaceutical Sciences of the International Pharmaceutical Federation, the Organizing Committee for the Millennial World Congress of Pharmaceutical Sciences, and as a member of the FDA Generic Drugs Advisory Committee and the FDA Science Board. In 2011, I completed a term as a member of the National Research Council Biodefense Standing Committee for the Department of Defense and in 2012 I completed a 9-year term as a member of the Institute of Medicine, Forum on Drug Discovery, Development and Translation. I presently serve on the Boards of Directors of the American Foundation for Pharmaceutical Education, Impax Laboratories Inc. and Chair of the Board of Directors of Medicines360.

III. Previous Testimony and Compensation

12. Since 2011, I have testified as an expert at trial or by deposition in the following matters:

a. *Roxane Laboratories, Inc. v. SmithKline Beecham d/b/a GlaxoSmithKline*, Case No. 09-cv-1638, Eastern District of Pennsylvania.

b. *Selina Thomas v. ALZA Corporation, et al.*, C.A. 10-CV-12037, U.S. District Court for the District of Massachusetts

c. *Nuvaring Products Liability Litigation* Case No. 4:08-MDL-1964-RWS U.S. District Court for the Eastern District of Missouri, Eastern Division

d. *Prograf Antitrust Litigation* Case No. 1:11-cv-2242 RWZ; U.S. District Court for the District of Massachusetts

13. My fees for time spent on his matter are $750 per hour for consultation through signing of an Expert Report, $1,500 per hour for deposition and deposition preparation, and $1,875 per hour for trial and trial preparation. My fees are not related in any way to the outcome of this litigation.

IV. Materials Considered

14. In forming the opinions, I have relied on my education, background, and experience, have reviewed and considered relevant portions of the '499 and '712 patents, as well as other documents cited or listed in this report, and have considered documents produced in this case, discovery responses, and testimony provided by the parties during the course of the litigation.

15. As this case progresses, I expect to review additional documents. I may rely on these documents, as well as other documents that have been marked as exhibits by the parties, or any deposition or trial testimony in this case, to support my opinions at trial. I reserve the right to supplement my opinions expressed herein in light of any additional materials, including opinions expressed by other witnesses and/or other evidence that may be provided to me after submission of this Report.

16. Documents I reviewed and relied on in forming the opinions set forth in this report are listed in Exhibit B.

V. Summary of Opinions

A. Patients That Use SOVALDI Infringe the Asserted Patents

17. It is my opinion that administration of Gilead's SOVALDI drug product for treatment of HCV infection, in accordance with the directions in the package insert, infringes claim 1 of the '499 patent.

18. It is my opinion that administration of Gilead's SOVALDI drug product for treatment of Hepatitis C Virus (HCV) infection in patients who are also being treated with ribavirin or with ribavirin and pegylated interferon, in accordance with the directions in the package insert, infringes claim 2 of the '499 patent.

19. It is my opinion that patients that use Gilead's SOVALDI drug product infringe claims 1-3, 5, 7 and 9-11 of the '712 patent.

B. Gilead's Sale of SOVALDI with the Prescribing Directions in the SOVALDI Package Insert Induces and Contributes to Infringement of the Asserted Patents

20. It is my opinion that by selling its SOVALDI drug product with the prescribing directions in the SOVALDI package insert, Gilead induces and contributes to infringement of claims 1 and 2 of the '499 patent and claims 1-3, 5, 7 and 9-11 of the '712 patent.

C. Patients That Use HARVONI Infringe the Asserted Patents

21. It is my opinion that administration of Gilead's HARVONI drug product for treatment of HCV infection, in accordance with the directions in the package insert, infringes claim 1 of the '499 patent.

22. It is my opinion that patients that use Gilead's HARVONI drug product infringe claims 1-3, 5, 7 and 9-11 of the '712 patent.

D. Gilead's Sale of HARVONI with the Prescribing Directions in the HARVONI Package Insert Induces and Contributes to Infringement of the Asserted Patents

23. It is my opinion that by selling its HARVONI drug product with the prescribing directions in the HARVONI package insert, Gilead induces and contributes to infringement of claim 1 of the '499 patent and claims 1-3, 5, 7 and 9-11 of the '712 patent.

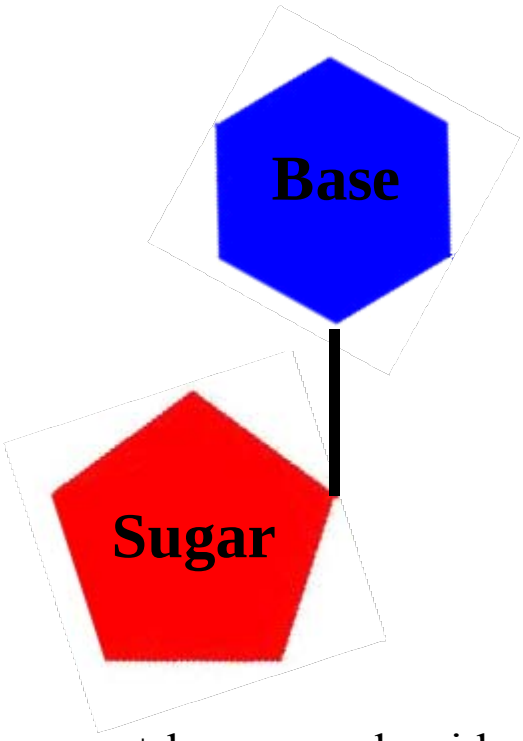
VI. Technological Background

The following background is provided as general scientific information to assist the Court. There may be exceptions or caveats to the scientific statements made here, but I provide the general concepts only to be concise. I reserve the right to use certain graphic and/or demonstrative materials to illustrate my testimony at trial.

A. Nucleosides and Nucleotides

24. Nucleosides are synthesized by self-replicating living systems, including humans.

25. Naturally occurring nucleosides are comprised of a sugar group (or sugar moiety) bound to a nucleobase (or "base") by a glycosidic bond. A nucleobase is an aromatic heterocyclic compound. The general structure of a nucleoside can be schematically represented as shown in Figure 1 below.



sugar + base = nucleoside

Figure 1

26. Nucleosides are components of both deoxyribonucleic acid (DNA) and ribonucleic acid (RNA). The sugar component of the nucleosides in DNA is 2'-deoxyribose. 2'-Deoxyribose contains five carbon atoms, four of which, together with an oxygen atom, form a five-membered ring. The fifth carbon atom is outside the ring, bearing a hydroxyl ("OH") group. The natural configuration of 2'-deoxyribose is referred to as the "D-configuration". The chemical structure of naturally occurring D-2'-deoxyribose can be depicted as shown in Figure 2 below. Figure 2 shows D-2'-deoxyribose with the carbon atoms numbered from 1' to 5' in a clockwise fashion, with the 5' carbon extending beyond the ring.

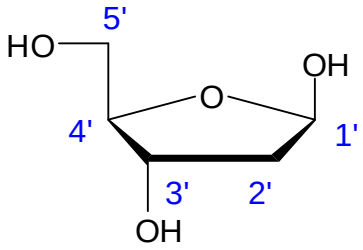


Figure 2

27. Pyrimidine nucleobases are 6-membered aromatic rings (four carbon atoms and two nitrogen atoms). In DNA, two different pyrimidine rings are present, thymine and cytosine. These are depicted in Figure 3 below. The positions of the pyrimidine bases are assigned non-prime numbers as shown in Figure 3.

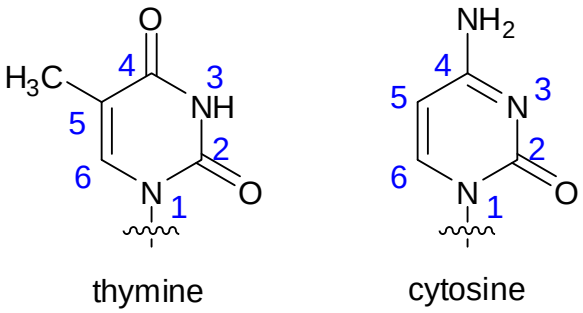


Figure 3

28. Purine nucleobases are bicyclic aromatic ring systems. In DNA, two purine rings are present, adenine and guanine. These are depicted in Figure 4 below. Purine bases are assigned non-prime numbers as shown in Figure 4 below.

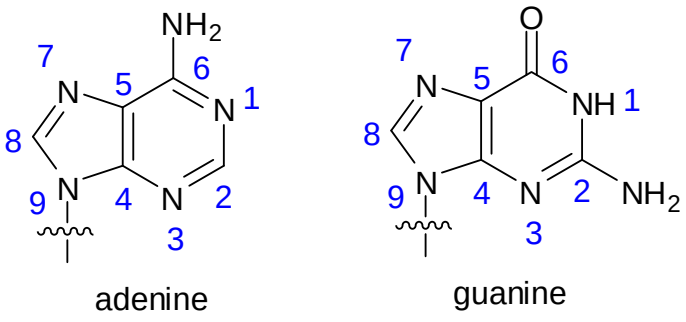


Figure 4

29. In contrast to DNA, the sugar component of RNA is the naturally occurring carbohydrate compound ribose. As compared to D-2'-deoxyribose of DNA, naturally occurring ribose contains a hydroxy group at the 2'-"down" position as shown in Figure 5 below.

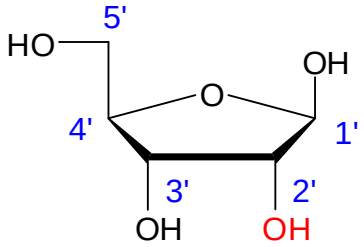
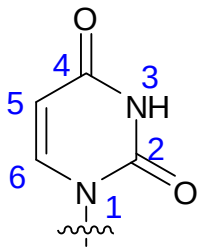


Figure 5

30. The purine bases found in RNA are identical to those in DNA, that is, adenine and guanine. RNA nucleosides also contain the pyrimidine base cytosine but the pyrimidine base uracil, depicted in Figure 6 below, replaces the thymine found in DNA.

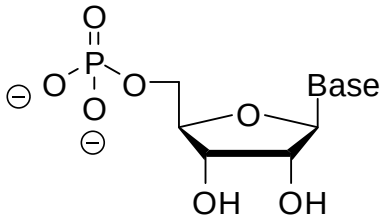


uracil

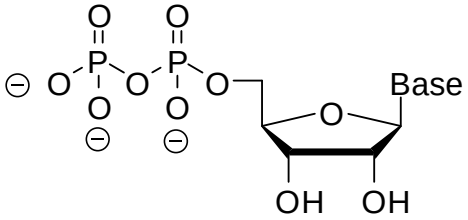
Figure 6

31. Naturally occurring nucleotides are comprised of a nucleoside (2'-deoxyribonucleoside in DNA, or ribonucleoside in RNA) to which at least one phosphate group is covalently bonded to the 5'- position of the sugar group. At the 5'-position of the sugar group, one or more phosphate groups can be added. The monophosphate has one phosphate added, the diphosphate has two phosphates added, and the triphosphate has three phosphates added.

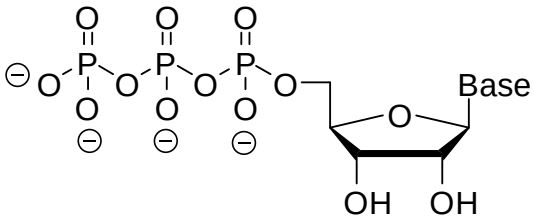
32. Figure 7 below depicts a 5'-ribonucleoside mono-, di- and triphosphate. Nucleotides are named by reference to the number of phosphate groups attached to the sugar ring.



5-ribonucleoside monophosphate



5-ribonucleoside diphosphate

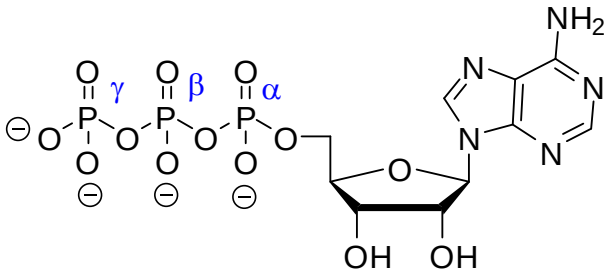


5-ribonucleoside triphosphate

Figure 7

33. *In vivo*, the process by which phosphate groups are added (covalently bonded) to the sugar group of a nucleoside (both ribonucleoside and 2'-deoxyribonucleoside) to form a nucleotide is known as phosphorylation.

34. Phosphorylation is an enzyme-catalyzed reaction in which a phosphate group from an activated phosphate donor is transferred to the oxygen atom attached to the 5'-position of the ribonucleoside. *In vivo*, phosphorylation is catalyzed by enzymes called nucleoside kinases which use adenosine triphosphate (ATP) as the activated phosphate donor. ATP is a 5'-ribonucleoside triphosphate where the nucleobase is adenine. Figure 8 below depicts ATP.



adenosine triphosphate (ATP)

Figure 8

By convention, the three phosphate groups of ATP are referred to as α-phosphate, β-phosphate and γ-phosphate, as shown in Figure 8 above.

35. The first step in the enzyme-catalyzed reaction between a naturally occurring ribonucleoside and ATP is shown in Figure 9 below.

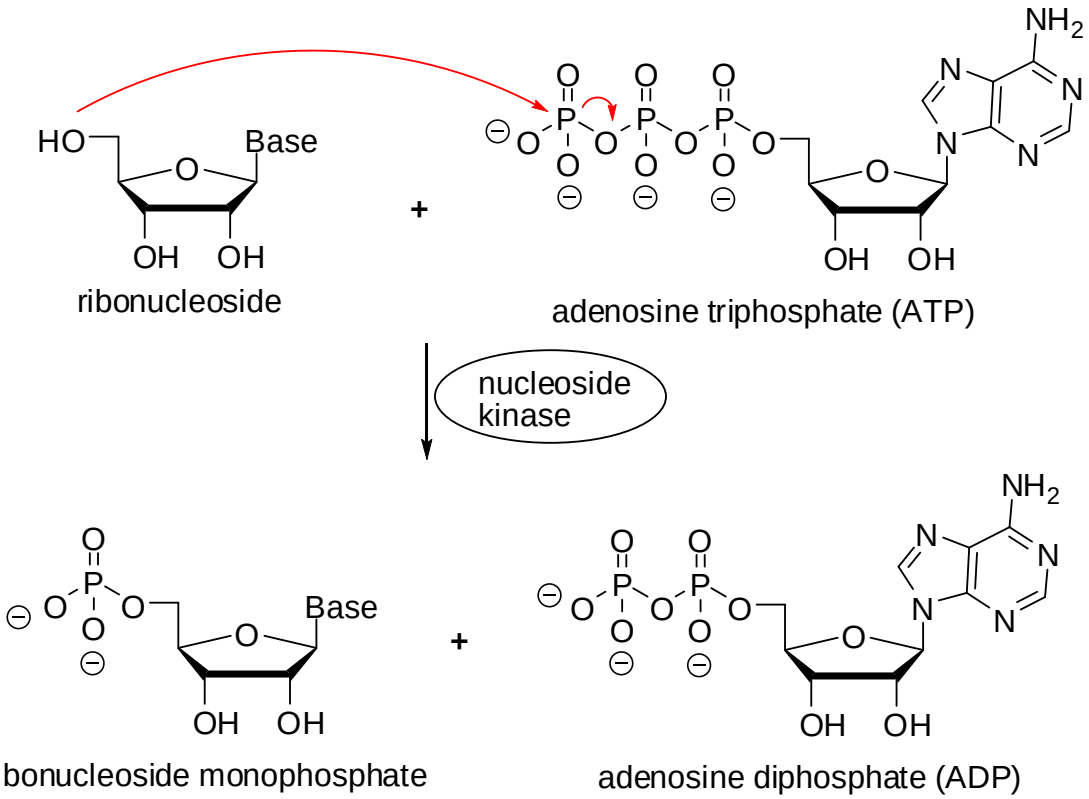


Figure 9

36. In the reaction depicted in Figure 9 above, the ribonucleoside and ATP are brought into close proximity in the active site of the nucleoside kinase enzyme. This allows the oxygen atom in the 5'-hydroxy group of the ribonucleoside to attack the γ-phosphate of adenosine triphosphate, leaving a phosphate group covalently bonded to the 5'-position of the ribonucleoside. ATP loses one phosphate group, becoming adenosine diphosphate (ADP) in the process.

37. *In vivo*, the 5'-ribonucleoside monophosphate then undergoes two further phosphorylation reactions to form, first, the 5'-ribonucleoside diphosphate and, finally, the 5'-ribonucleoside triphosphate. The stepwise process of the formation of the 5'-ribonucleoside triphosphate is shown in Figure 10 below.

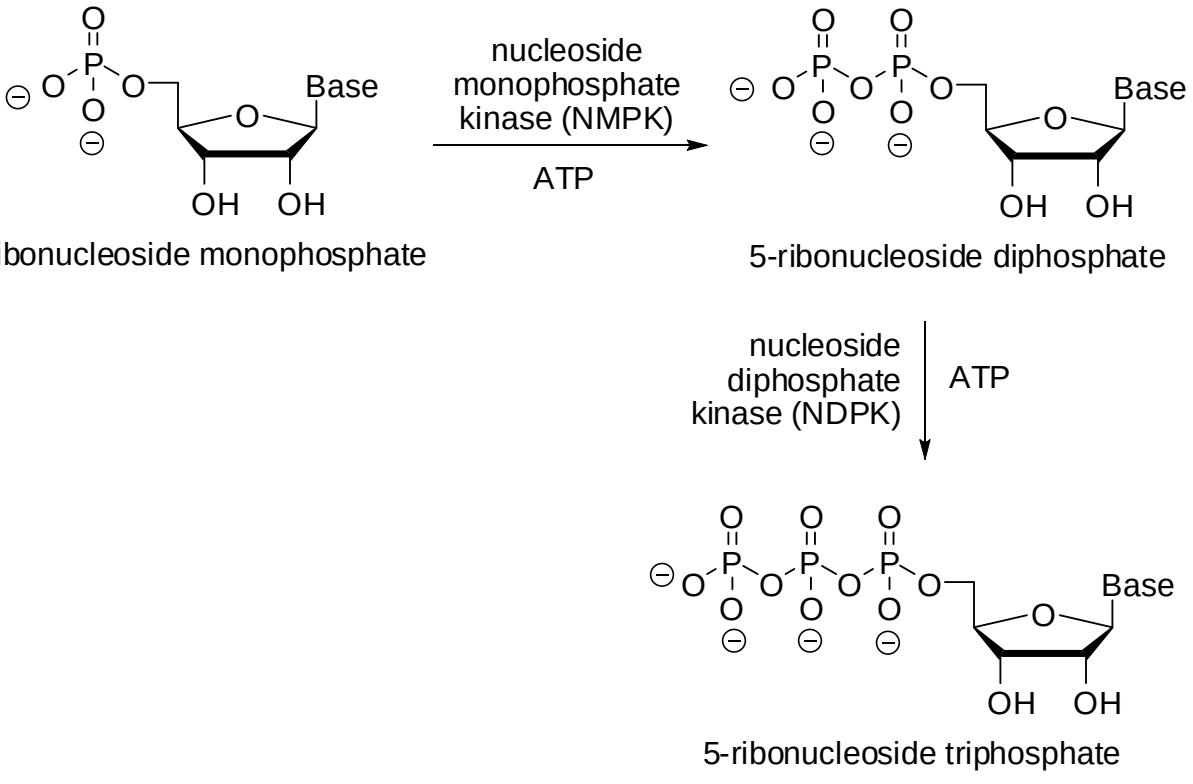


Figure 10

38. RNA is composed of ribonucleoside monophosphates (also called ribonucleotides). The individual ribonucleotides are linked to form a strand (or chain) through the 3',5'-phosphate diester bonds that form between the 5'-phosphate group of one ribonucleotide and the 3'-hydroxyl group of the adjacent ribonucleotide. This is shown in Figure 11 below.

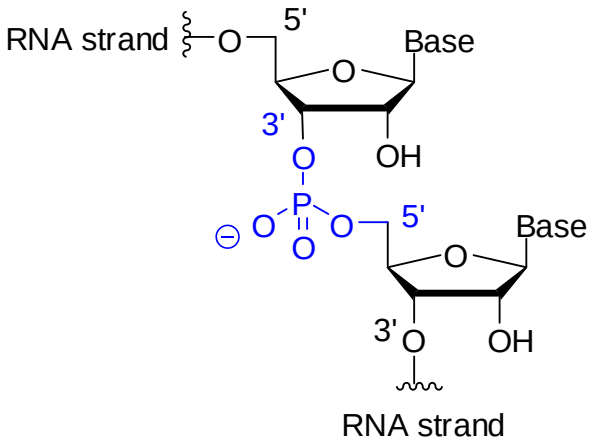


Figure 11

39. 5'-Ribonucleoside monophosphates are the building blocks of RNA. Biological RNA synthesis is catalyzed by enzymes known as RNA polymerases, which actively join 5'-ribonucleoside triphosphates to form a strand of RNA. Similarly, DNA synthesis is catalyzed by enzymes known as DNA polymerases.

B. Nucleoside and Nucleotide Analogs

40. I have been asked to briefly explain my understanding of the terms "nucleoside analog" and "nucleotide analog" and to describe my understanding of the mechanism by which such compounds act as antiviral agents (or antiviral drugs) in the treatment of hepatitis C virus (HCV) infection in humans.

41. Above, I described naturally occurring nucleosides and nucleotides. These compounds can be chemically altered at almost every position of the sugar ring or the heterocyclic aromatic base. Such alterations include substitution of one or more atom(s) or group(s) of atoms in the sugar or base or replacement of one base or sugar for another, and/or removal of atom(s) and/or group(s), resulting in a compound referred to as an "analog".

42. Nucleoside and nucleotide analogs have for many years been studied and medically used in the treatment of viral infection in humans, including HCV infection.

C. Hepatitis C Virus ("HCV")

43. Viruses infect living things and make use of their host's cellular reproduction mechanisms to reproduce themselves. Viruses have either DNA or RNA as their genetic material, and accordingly can be classified as DNA viruses or RNA viruses. Individual viruses carry their own nucleic acid polymerase, called viral polymerase, to replicate their genetic material.

44. In general, a viral particle (a "virion") consists of: 1) the genetic material (DNA or RNA); 2) a protein coat that protects the genetic material; and in some cases 3) an envelope that surrounds the protein coat when they are outside a cell. Once inside the host cell, the virus' genetic material co-opts the target cell's reproductive machinery to create more viral components and thus more virions. In the host cell, the viral nucleic acid strand is translated into a viral protein. Production of viral protein is the first step in the replication of new virus. One of the viral proteins, the viral polymerase, initiates replication of the viral genome.

45. The Flaviviridae family of viruses includes pestiviruses (which cause various cattle and swine diseases such as BVDV), flaviviruses (such as West Nile virus) and hepaciviruses (such as

hepatitis C virus or HCV). While some viruses carry with them their own phosphorylating kinase, Flaviviridae do not and, as such, must rely upon the cell's kinase for phosphorylation in order to replicate. Flaviviridae, including HCV, are single stranded RNA viruses with positive-sense polarity, and replicate their genome using replicase protein complexes to synthesize a complementary replicative negative strand. The positive-sense genome of Flaviviridae means that they can use their RNA genome as cellular messenger RNA (mRNA) for translation of viral proteins.

46. HCV is a single-stranded RNA virus that infects the liver cells of humans. Like all viruses, HCV is unable to self-replicate and instead utilizes the host (i.e. human liver) intracellular machinery in order to replicate. Replication of HCV RNA involves a viral RNA-dependent-RNA-polymerase called NS5B that synthesizes new RNA strands using 5'-ribonucleoside triphosphates from the host liver cell as its substrate.

47. The primary route of HCV entry into the body is through the skin (percutaneous), although infection through mucous membranes (permucosal) is also possible. Experimentally, HCV infection has been caused by intravenous injection of HCV virions or injection of HCV genomic RNA into the liver (intrahepatic). HCV replication occurs primarily in hepatocytes, a major cell of the liver.

48. If left untreated, HCV infection can spontaneously resolve or persist as chronic HCV infection. Chronic HCV most clearly causes morbidity and mortality by either liver failure and/or liver cancer. (S.C. Ray *et al.*, "Hepatitis C Virus," *In* Fields Virology, 6th Edition, D.M. Knipe and P.M. Howley (eds.) Lippincott Williams & Wilkens, Philadelphia, 2013, Chapter 27, p. 804) (Exhibit C)

49. As of 2004, there were an estimated 185 million persons in the world infected with HCV, representing approximately 2.2% of the world population. (*Id*. at p. 805) In the United States, approximately 3 million persons were infected with chronic HCV. (*Id*. at p. PO 806) There are seven known genotypes of HCV virus. Some genotypes persist in specific regions in the world, for example genotypes 4 and 5 are found in north-central and southern Africa. (*Id*. at 806) Some genotypes show resistance to previous HCV treatments, for example, genotypes 1 and 4 are less responsive to treatment with interferons than other genotypes. (*Id*. at p. 808)

50. Antiviral agents are designed to interfere with some aspect of the viral process. One approach is to interfere with a virus's ability to bind to or enter a host cell. Another approach is to target the viral protease to prevent the production of the viral functional proteins, and thus, inhibit the packaging or exportation of the virus from a cell. A further alternative is to target the viral polymerase, which is responsible for synthesizing the viral nucleic acid strand. A similar strategy is to use a nucleoside/nucleotide analog to interfere with chain elongation of the viral nucleic acid and thus prevent the virus from replicating.

51. NS5B-catalyzed RNA synthesis is an ideal target for intervention. One strategy developed for such intervention involves the use of 5'-nucleoside triphosphate analogs. In the liver cell, such compounds can exhibit sufficient similarity to naturally occurring 5'-ribonucleoside triphosphates to be recognized by NS5B as a substrate, leading to their incorporation into the growing viral RNA chain. However, by the modifications on the 5'-nucleoside triphosphate analog the next nucleotide is prevented from being integrated on the 3′-OH group by the formation of a phosphate diester bond. Thus, the bonding of a further nucleotide from the respective 5'-ribonucleoside triphosphate is prevented, and thus, termination

of the viral RNA synthesis (replication) is caused, wherein further spreading of the infection is prevented.

52. 5'-Nucleoside triphosphate analogs may also demonstrate antiviral activity by direct inhibition of NS5B, wherein the termination of an RNA chain occurs.

D. Prodrugs

53. Prodrugs are "derivatives of a drug molecule that require a transformation within the body to release the active drug." (V.J. Stella *et al*., "Prodrugs. Do They Have Advantages in Clinical Practice?" *Drugs, 29:* 455-473 (1985)) (Exhibit D).

54. A prodrug strategy can be employed to increase the likelihood and amount of a drug reaching its intended target.

55. For example, prodrugs can be pharmacologically inactive compounds, designed to maximize the amount of the active species that reaches its site of action. Inactive prodrugs can be converted rapidly to biologically active metabolites, often by hydrolysis of an ester or amide linkage. (L.Z. Benet, D.L. Kroetz and L.B. Sheiner. "Pharmacokinetics: The Dynamics of Drug Absorption, Distribution, and Elimination" *In* Goodman and Gilman's The Pharmacological Basis of Therapeutics, Ninth Edition, J.G. Hardman, L.E. Limbird, P.B. Molinoff, R.W. Ruddon and A.G. Goodman (eds.), McGraw-Hill, New York, 1996, Chapter 1, p. 11) (Exhibit E).

56. The site of action for anti-HCV drugs is the intracellular environment of the liver cell where viral RNA replication (infection) takes place. For a compound to reach this intracellular environment after oral administration, it must first be absorbed into the bloodstream and distributed through the body. It must then be "taken up" by the liver cell, that is, it must pass through the liver cell membrane into the intracellular environment.

57. One aim of prodrug design for nucleotides is to mask (or protect) the 5'-phosphate group of the nucleotide analog to prevent dephosphorylation (loss of phosphate groups) in the bloodstream. As shown in Figures 12 and 13 below, the chemical modifications applied to the compounds can also neutralize the negative charges of the 5'-phosphate group resulting in the formation of a neutral (uncharged) compound that more readily crosses the cellular membrane.

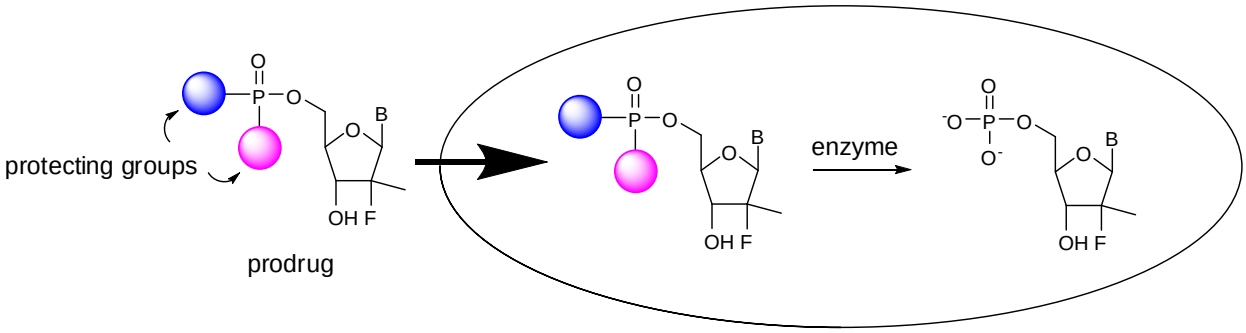


Figure 12

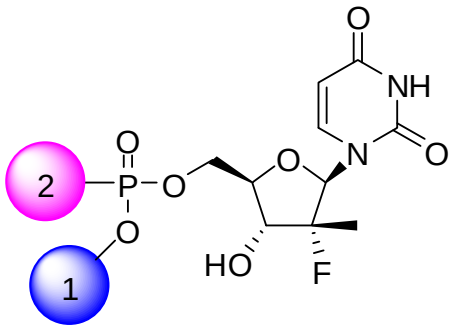


Figure 13

VII. Gilead's Sofosbuvir Products

A. Gilead's New Drug Applications for SOVALDI and HARVONI

58. It is my understanding that Gilead filed two New Drug Applications ("NDA") with the U.S. Federal Food and Drug Administration ("FDA") seeking FDA approval to commercialize its SOVALDI (sofosbuvir) and HARVONI (ledipasvir/sofosbuvir) drug products (collectively the "Sofosbuvir Products") for the treatment of HCV infection. See Excerpts from Gilead NDAs GILEAD00000001, GILEAD00083995, GILEAD00086378, GILEAD00086393, GILEAD00086410, GILEAD00086488, GILEAD00087905, GILEAD00088221, GILEAD00088464, GILEAD00089105, GILEAD02418079, GILEAD02418082, GILEAD02418085, GILEAD02592816, GILEAD02593527, GILEAD02593884, GILEAD02594242, GILEAD02594262, GILEAD02594288, GILEAD02594446, GILEAD02597307, GILEAD02597708; *see also* E. Murakami *et al.,* "Mechanism of Activation of PSI-7851 and Its Diastereoisomer PSI-7977," *J. Biol. Chem*. *285*: 34337-34347 (2010) ("Murakami") (GILEAD00030406-416) (Exhibit F).

59. SOVALDI and HARVONI are both approved for the treatment of HCV infection. A review of the FDA's electronic Orange Book indicates that there is no other approved use for either SOVALDI or HARVONI.

B. The Structure of Sofosbuvir

60. The chemical structure of sofosbuvir is shown in Figure 14 below.

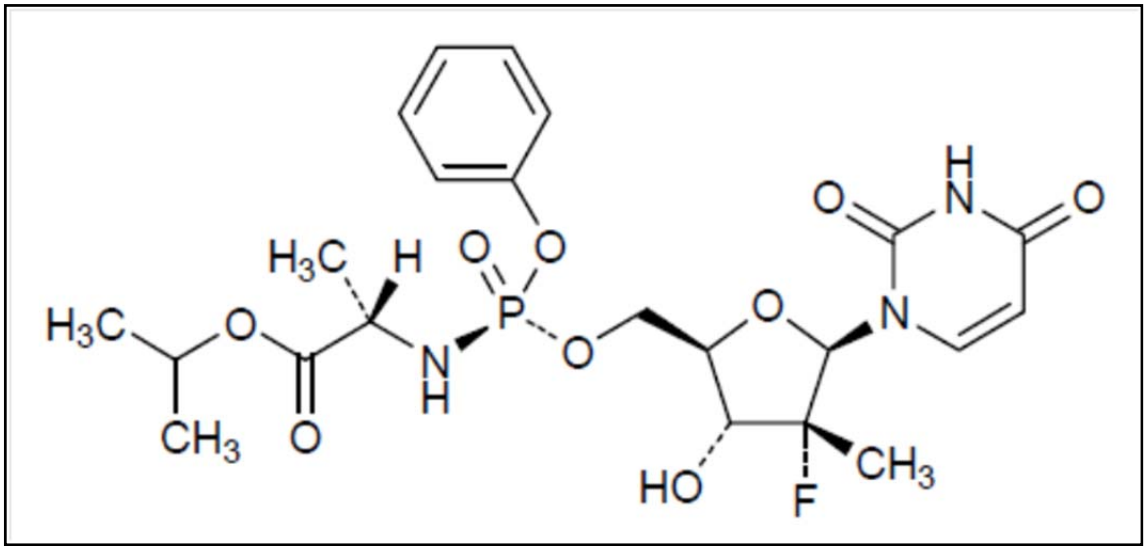


Figure 14

61. The compound, which is described by the formula of Figure 14, is a substance that is known today as sofosbuvir. Sofosbuvir can be described as a phosphoramidate prodrug of the 5′-phosphate derivative of the β-D-2′-deoxy-2′-α-fluoro-2′-β-C-methyluridine nucleotide.

62. Sofosbuvir is a nucleotide prodrug, in which one oxygen atom of the 5'-phosphate group is masked by the attachment of a phenyl group with the formation of a phenol ester. The compound is modified further by the replacement of an oxygen atom of the 5' phosphate group by the nitrogen (N) atom of the isopropyl L-alanine amino acid ester. In Figure 15 below, the structure of Sofosbuvir is marked to show the phenol ester group (yellow) and the isopropyl L-alanine group (blue).

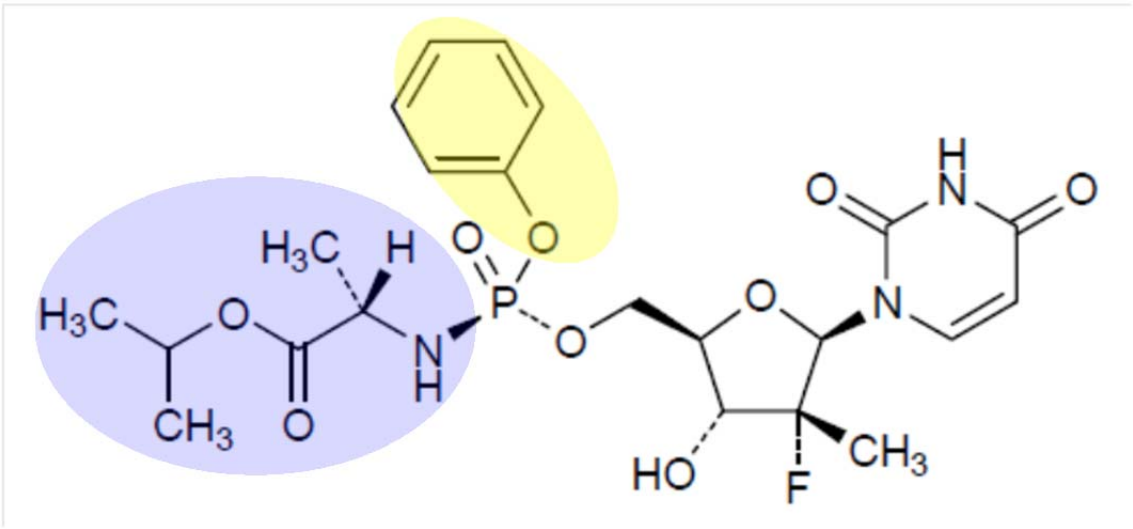


Figure 15

63. The basic formula of a nucleotide prodrug, comprising a phenol ester group and an isopropyl L alanine group, which is known as a phosphoramidate nucleotide prodrug, was developed by Professor Chris McGuigan and described in C. McGuigan *et al*, "Aryl Phosphate Derivatives of AZT Inhibit HIV Replication in Cells Where the Nucleoside Is Poorly Active" *Bioorganic & Medicinal Chemistry Letters*, *2*: 701-704 (1992).

C. The Metabolism of Sofosbuvir

64. As directed in the prescribing information for SOVALDI (Exhibit G) and HARVONI (Exhibit H), sofosbuvir is taken orally by the patient. *See* GILEAD00000953 (Exhibit G) and GILEAD04424643 (Exhibit H).

Once in the body, sofosbuvir undergoes metabolism as detailed below in Figures 16 and 17. In Figure 16, I reproduce Fig. 7 from Murakami using the compound numerical designations in that paper. In Figure 17, I reproduce the "Intracellular Metabolic Pathway for Sofosbuvir" that is

found in a number of places in the Gilead NDAs (for example, GILEAD 00084002) using the numerical designations in the Gilead NDA.

65. In the first step of the metabolism of sofosbuvir (PSI-7581 in Fig. 16; SOF in Fig. 17), the phosphoramidate moiety is converted in the liver into a monophosphate nucleotide analog (PSI-7411 and GS-606965). The monophosphate nucleotide analog is then further metabolized into a diphosphate nucleotide analog (PSI-7410 and GS-607596) that in turn is metabolized into a triphosphate nucleotide analog (PSI-7409 and GS-461203), which is the pharmacologically active species.

66. Since the triphosphate nucleotide analog is the active molecule, the sequential conversion of sofosbuvir to its monophosphate, diphosphate and triphosphate metabolites is essential in order to provide the desired pharmacological activity for treating HCV infection.

67. Figure 17, taken from Gilead's NDAs, depicts the same pathway as Figure 16, taken from Murakami, but does not expressly depict the formation of the diphosphate nucleotide analog, but rather shows two kinase steps, without depicting the diphosphate nucleotide analog between those steps. The text at GILEAD00086397, "Sofosbuvir is a nucleotide prodrug of 2'-deoxy-2'-fluoro-2'-C-methyluridine monophosphate that is converted to the active uridine triphosphate form (GS-461203) within the hepatocyte (Figure 1)," acknowledges the pathway in which the diphosphate is depicted in Murakami.

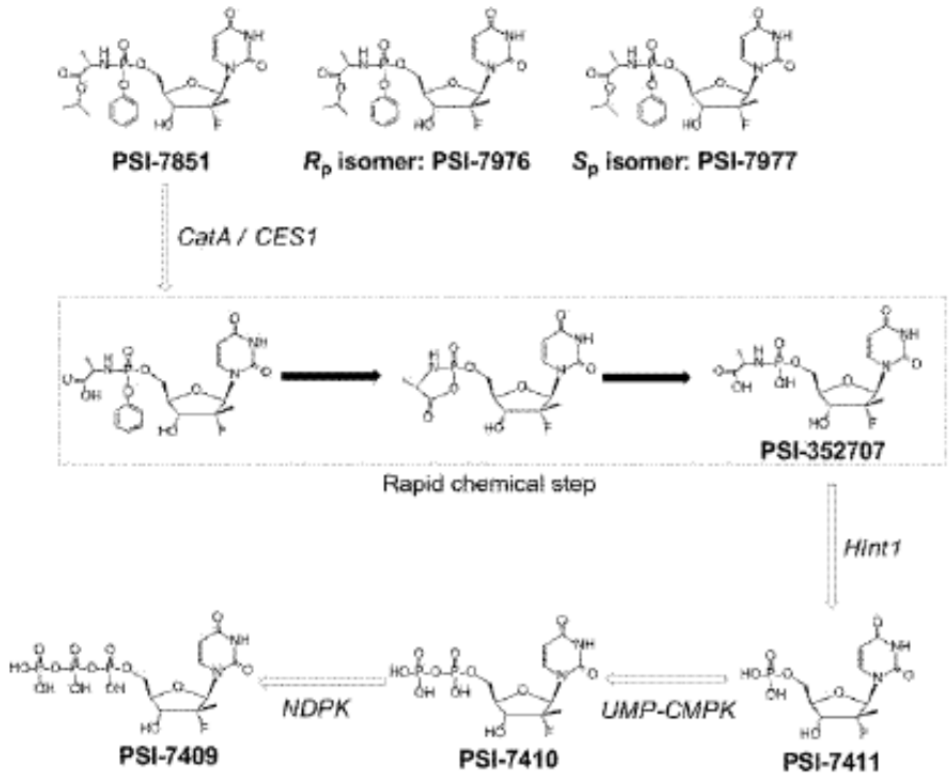


Figure 16 (Figure 7 from Murakami)

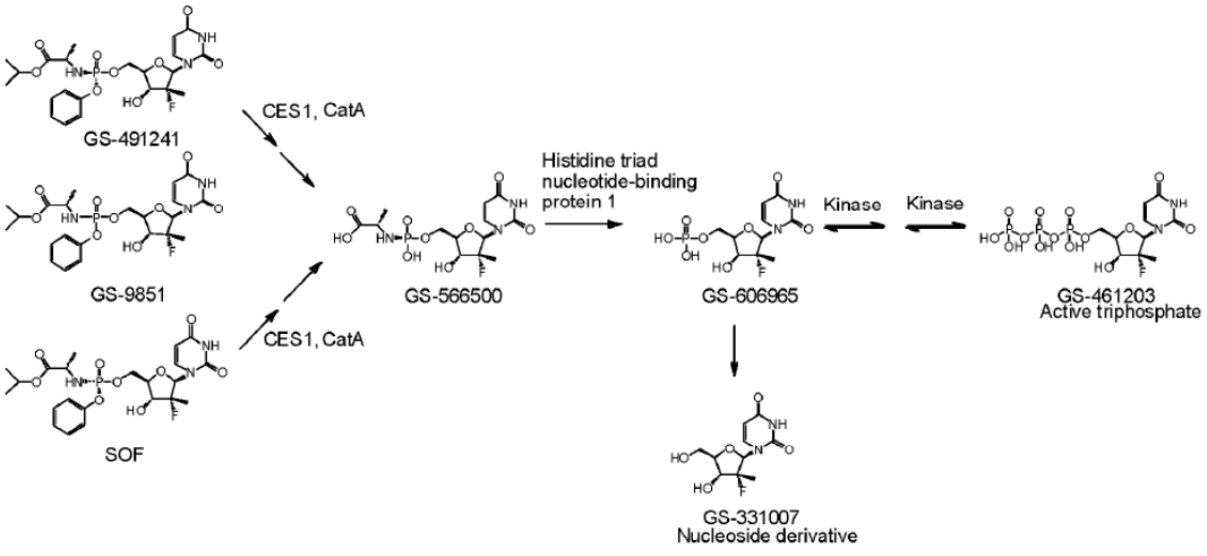


Figure 17 (GILEAD00084002)

VIII. Applicable Legal Principles

68. I am not an expert on patent law. I have been informed of, and have assumed, various legal principles relevant to the analysis of patent claim infringement. I understand that an infringement analysis is a two-step process. In the first step, the claims of the patent are construed. I understand that the Court has construed certain claims of the patents-in-suit and set forth those constructions in the May 1, 2015 Order construing claims in the '499 and '712 patents. In the second step, the claims, as construed, are compared to the accused products.

A. Direct Infringement

69. With respect to "direct infringement," I have been informed by counsel that whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.

70. I understand that an accused product directly infringes a patent claim when that accused product includes each and every limitation of an asserted claim, that is, when all the limitations of the claim are literally present in the accused product.

71. I understand that an accused method directly infringes a patent claim when each and every limitation of an asserted claim is practiced, that is, when each of the steps of the method claim are literally practiced.

B. Induced Infringement

72. I have been informed by counsel that if a person or company actively induces another to infringe one or more claims of a patent, or sells a product with instructions that direct an infringing use, it is liable for inducing infringement of the one or more claims.

C. Contributory Infringement

73. With respect to contributory infringement, I have been informed by counsel that whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

IX. Infringement Of U.S. Patent No. 7,105,499

74. The '499 patent (attached as Exhibit I), entitled "Nucleoside Derivatives as Inhibitors of RNA-Dependent RNA Viral Polymerase," is directed to methods for treating HCV by administration of specified chemical compounds.

75. The HCV virion is an enveloped positive-strand RNA virus that encodes a polyprotein of about 3,010 amino acids. One of the non-structural proteins produced by the HCV gene is NS3, which cleaves the viral polyprotein to generate NS5B, the RNA-dependent RNA polymerase. HCV NS5B polymerase is required for the synthesis of a double-stranded RNA from a single-stranded RNA that serves as a template in the replication cycle of HCV. NS5B polymerase is, therefore, essential for HCV replication. ('499 patent, col. 2, lines 8-31). The '499 patent discloses treatment of HCV infection by administering compounds that inhibit the NS5B polymerase of HCV. (*Id*., col. 2, lines 32-40).

76. The claims of the '499 patent are directed to methods of treating HCV infection in a mammal by administering nucleoside analogs that are identified by means of a structural formula in claim 1.

77. A patient who ingests a pharmaceutical product that contains sofosbuvir *necessarily* metabolizes sofosbuvir into compounds that satisfy the structural formula in claim 1 of the '499 patent

78. I understand the Court has adopted the following definitions of terms that appear in the claims of the '499 patent in an Order dated May 1, 2015:

> The term "in combination with" means "together with," whether given separately at different times during the course of therapy or concurrently in divided or single combination forms.
>
> The term "compound" means a substance that consists of two or more chemical elements in union.
>
> The term "administering" means providing a compound of the invention or a prodrug of a compound of the invention to the individual in need.

79. I present my infringement analysis based on the meanings of these terms as set forth above. The results of my analysis are summarized in the claim chart attached as Exhibit K to this Report. I reserve the right to revise or supplement my analysis based on positions provided in Plaintiff's expert reports.

A. Administering SOVALDI for Treatment of HCV Infection infringes Claim 1 of the '499 Patent

1. SOVALDI contains sofosbuvir as the active ingredient

80. Sofosbuvir is the active ingredient in the SOVALDI product. (See GILEAD00000002)

2. SOVALDI is used to treat HCV infection

81. Claim 1 of the '499 patent is directed to a "method for treating hepatitis C virus (HCV) infection." The prescribing information in the SOVALDI package insert states that "SOVALDI is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen." (GILEAD00000952).

82. The prescribing information for SOVALDI directs that sofosbuvir be administered to an HCV-infected patient to treat the HCV infection. When SOVALDI is used in accordance with its accompanying directions, it is effective in treating HCV infection. (GILEAD00000952).

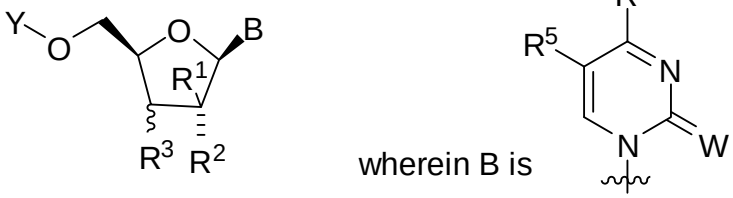
3. SOVALDI is administered to a mammal infected with HCV

83. Claim 1 of the '499 patent recites "administering to a mammal in need of such treatment." The prescribing information for SOVALDI directs that it is to be administered to patients with HCV infection, which are mammals. (GILEAD00000953).

84. Claim 1 of the '499 patent recites the administration of "a therapeutically effective amount of a compound of structural formula III, or a pharmaceutically acceptable salt or acyl derivatives thereof." The prescribing information for SOVALDI states that sofosbuvir is provided as a tablet containing 400 mg of sofosbuvir, which is a therapeutically effective amount of sofosbuvir. (GILEAD00000952).

4. Sofosbuvir is a prodrug of compounds of Formula III in claim 1

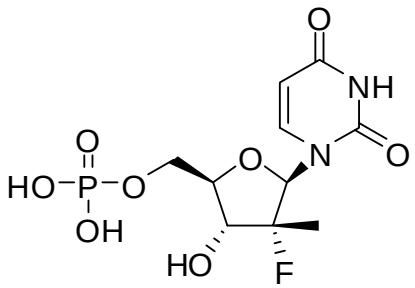
85. Claim 1 of the '499 patent recites that a compound of formula III is to be administered, where the choices for W, Y and R^x are specified in the claim.



Formula III

86. A patient who takes SOVALDI for treatment of HCV directly infringes claim 1 of the '499 patent because sofosbuvir is a prodrug that metabolizes in the body into one or more of the compounds of formula III set forth in that claim.

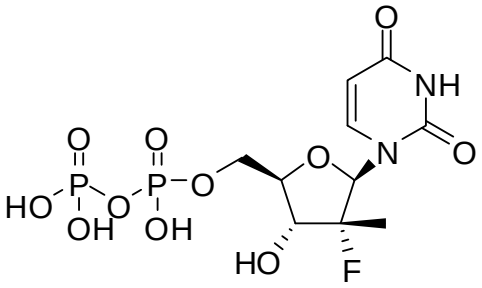
87. Sofosbuvir is metabolized in the body to form the following monophosphate compound that falls within formula III of claim 1 of the '499 patent:



See Compound GS-606965 at GILEAD00084002; see also Compound PSI-7411, Murakami at 34344.

88. This compound falls within formula III in the following way: W = O; $R^1 = CH_3$ ("C_{1-4} alkyl"); R^2 = fluoro; R^3 = OH; R^6 = OH; R^5 = H; and Y = PO_3H_2. This satisfies formula III where Y = $P(O)R^9R^{10}$ and R^9 and R^{10} are both hydroxy.

89. Sofosbuvir is further metabolized in the body to form the following diphosphate compound:

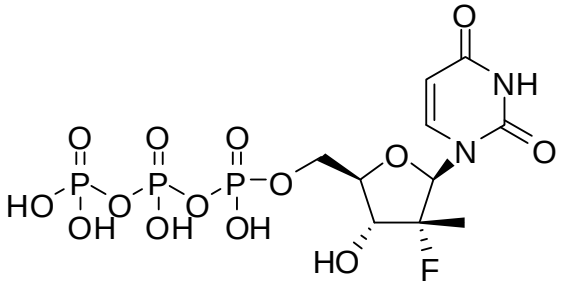


See Compound PSI-7410, Murakami at 34344, and the implied figure between the two kinase arrows at GILEAD00084002.

90. This compound falls within formula III in the following way: W = O; Y = $P_2O_6H_3$; R^1 = CH_3 ("C_{1-4} alkyl"); R^2 = fluoro; R^3 = OH; R^6 = OH; R^5 = H.

91. A patient who takes SOVALDI directly infringes claim 1 of the '499 patent because sofosbuvir metabolizes in the body into a compound of formula III.

92. Sofosbuvir is also metabolized in the body to form the following triphosphate compound:



See Compound GS-461203 at GILEAD00084002; see also Compound PSI-7409, Murakami at 34344.

93. This compound falls within formula III in the following way: W = O; Y = $P_3O_9H_4$; R^1 = CH_3 ("C_{1-4} alkyl"); R^2 = fluoro; R^3 = OH; R^6 = OH; R^5 = H.

94. Providing SOVALDI to a patient for treatment of HCV infection directly infringes claim 1 of the '499 patent because sofosbuvir metabolizes in the body into compounds of formula III.

B. Sale of SOVALDI with Directions for its Administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 1 of the '499 Patent

95. Gilead induces and contributes to infringement of claim 1 of the '499 patent by selling SOVALDI with directions for its administration to treat HCV infection, knowing that sofosbuvir is a prodrug that will be metabolized into compounds of formula III set forth in claim 1 of the '499 patent.

96. SOVALDI is not approved by the FDA for any use other than treating HCV infection. Gilead contributes to the infringement of claim 1 of the '499 patent because Gilead is aware that sofosbuvir metabolizes into compounds of formula III of claim 1 of the '499 patent, as shown by Gilead's scientific publications and submissions to the FDA, and there is no FDA-approved use for SOVALDI other than for treating HCV infection.

C. Use of SOVALDI in Accordance with the Instructions in the Package Insert Infringes Claim 2 of the '499 Patent

97. The discussion of the ingestion of Sovaldi with respect to claim 1 of the '499 patent set forth above applies to Claim 2 of the '499 patent, as well.

98. Claim 2 of the '499 patent recites that the compound of formula III is administered "in combination with a therapeutic amount of another agent active against HCV infection selected from the group consisting of ribavirin; levovirin; thymosin alpha-1; an inhibitor of NS3 serine protease; an inhibitor of inosine monophosphate dehydrogenase; and interferon-α or pegylated interferon-α."

99. The prescribing information for SOVALDI states that SOVALDI is "a component of a combination antiviral treatment regimen." (GILEAD00000952). The prescribing information

for SOVALDI further directs the use of SOVALDI "in combination with ribavirin or in combination with pegylated interferon and ribavirin for the treatment of CHC." (*Id.*).

100. Administering SOVALDI to a patient with HCV who is also being treated with ribavirin and/or pegylated interferon, as instructed in the package insert for SOVALDI, directly infringes claim 2 of the '499 patent because sofosbuvir metabolizes in the body into one or more of the compounds of formula III set forth in claim 1 of the '499 patent.

D. Gilead's Sale of SOVALDI with Directions for its Administration to Treat HCV Infection in Combination with Ribavirin and/or Pegylated Interferon Induces and Contributes to Infringement of Claim 2 of the '499 Patent

101. The discussion of the administration of SOVALDI with respect to claim 1 of the '499 patent set forth above applies to Claim 2 of the '499 patent, as well.

102. The prescribing information for SOVALDI states that SOVALDI is "a component of a combination antiviral treatment regimen." (GILEAD00000952). The prescribing information for SOVALDI further states that sofosbuvir should "be used in combination with ribavirin or in combination with pegylated interferon and ribavirin for the treatment of CHC." (*Id.*).

103. Gilead induces and contributes to infringement of claim 2 of the '499 patent by selling SOVALDI with directions for its administration to treat HCV infection in combination with ribavirin and/or pegylated interferon, knowing that the resulting metabolism of sofosbuvir will result in formation of one or more of the compounds of formula III set forth in claim 1 of the '499 patent.

104. SOVALDI is not approved by the FDA for any use other than treating HCV infection in combination with ribavirin and/or pegylated interferon. Gilead contributes to the infringement of claim 2 of the '499 patent because Gilead is aware that sofosbuvir metabolizes into one or more

of the compounds of formula III of claim 2 of the '499 patent, as shown by Gilead's scientific publications and submissions to the FDA, and there is no FDA-approved use for SOVALDI other than administering it in combination with these agents for treating HCV infection.

E. Administering HARVONI for Treatment of HCV Infection Infringes Claim 1 of the '499 Patent

1. HARVONI contains sofosbuvir as an active ingredient

105. Sofosbuvir is one of the active ingredients in the HARVONI product. (See GILEAD02418080)

2. HARVONI is used to treat HCV infection

106. Claim 1 of the '499 patent is directed to a "method for treating hepatitis C virus (HCV) infection." The prescribing information for HARVONI states that "HARVONI is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infections in adults." (GILEAD04424643).

107. The prescribing information for HARVONI directs that sofosbuvir is to be used to treat hepatitis C virus (HCV). When used according to labeled directions it is effective in treating HCV infection.

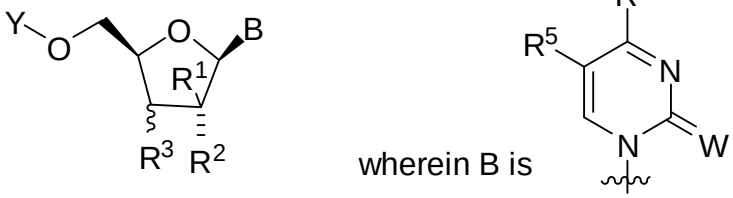
3. HARVONI is administered to a mammal infected with HCV

108. Claim 1 of the '499 patent recites "administering to a mammal in need of such treatment." The prescribing information for HARVONI discloses that sofosbuvir is to be administered to patients with chronic HCV infection, which are mammals. (GILEAD04424646).

109. Claim 1 of the '499 patent recites the administration of "a therapeutically effective amount of a compound of structural formula III, or a pharmaceutically acceptable salt or acyl derivatives thereof." The prescribing information for HARVONI states that the amount of sofosbuvir provided in the tablet is 400 mg, which is a therapeutically effective amount of sofosbuvir. (GILEAD04424646).

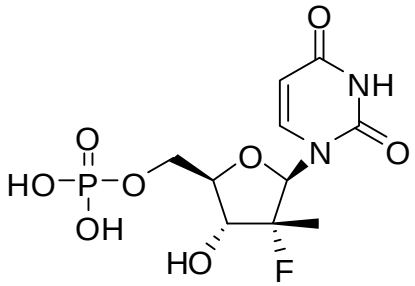
4. Sofosbuvir is a prodrug of compounds of Formula III in claim 1

110. Claim 1 of the '499 patent recites that a compound of formula III is to be administered, where the choices for W, Y and R^x are specified in the claim.



Formula III

111. Sofosbuvir is metabolized in the body to form the following compound that falls within formula III:

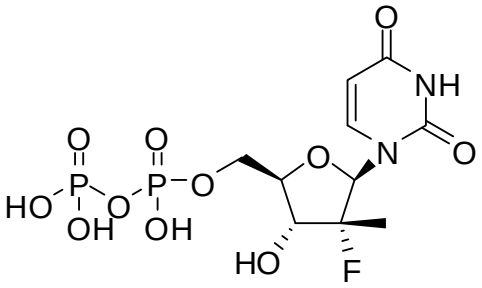


See Compound GS-606965 at GILEAD00084002; see also Compound PSI-7411, Murakami at 34344.

112. A patient who takes HARVONI for treatment of HCV directly infringes claim 1 of the '499 patent because sofosbuvir is a prodrug that metabolizes in the body into one or more of the compounds of formula III.

113. This compound falls within formula III in the following way: W = O; $R^1 = CH_3$ ("C_{1-4} alkyl"); R^2 = fluoro; R^3 = OH; R^6 = OH; R^5 = H; and Y = PO_3H_2. This satisfies formula III where Y = $P(O)R^9R^{10}$ and R^9 and R^{10} are both hydroxy.

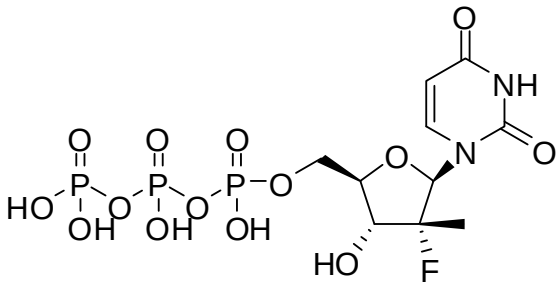
114. Sofosbuvir is also metabolized in the body to form the following compound that falls within formula III:



See Compound PSI-7410, Murakami at 34344, and the implied figure between the two kinase arrows at GILEAD00084002.

115. This compound falls within formula III in the following way: W = O; Y = $P_2O_6H_3$; R^1 = CH_3 ("C_{1-4} alkyl"); R^2 = fluoro; R^3 = OH; R^6 = OH; R^5 = H.

116. Sofosbuvir is also metabolized in the body to form the following compound:



See Compound GS-461203 at GILEAD00084002; see also Compound PSI-7409, Murakami at 34344.

117. This compound falls within formula III in the following way: W = O; Y = $P_3O_9H_4$; R^1 = CH_3 ("C_{1-4} alkyl"); R^2 = fluoro; R^3 = OH; R^6 = OH; R^5 = H.

F. Sale of HARVONI with Directions for its Administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 1 of the '499 Patent

118. Gilead induces and contributes to infringement of claim 1 of the '499 patent by instructing a patient to ingest HARVONI knowing that the resulting metabolism of sofosbuvir will result in one or more of the compounds of formula III that infringe claim 1 of the '499.

119. HARVONI is not approved by the FDA for any use other than treating HCV infection. Gilead contributes to the infringement of claim 1 of the '499 patent because Gilead's publications and submissions to the FDA acknowledge that sofosbuvir metabolizes into one or more of the compounds of formula III of claim 1 of the '499 patent, and there is no FDA-approved non-infringing use for HARVONI.

X. Infringement of U.S. Patent No. 8,481,712

120. The '712 patent (attached as Exhibit J), entitled "Nucleoside Derivatives as Inhibitors of RNA-Dependent RNA Viral Polymerase," is directed to chemical compounds that are useful for treating HCV infection.

121. The HCV virion is an enveloped positive-strand RNA virus which encodes a polyprotein of about 3,010 amino acids. One of the non-structural proteins produced by the HCV gene is NS3, which releases NS5B, the RNA-dependent RNA polymerase. HCV NS5B polymerase is

required for the synthesis of a double-stranded RNA from a single-stranded RNA that serves as a template in the replication cycle of HCV. NS5B polymerase is therefore essential for HCV replication. ('712 patent, col. 2, lines 19-41). The '712 patent discloses treatment of HCV infection by administering compounds that inhibit the NS5B polymerase of HCV. (*Id.*, col. 2, lines 42-50).

122. The claims of the '712 patent are directed to chemical compounds that are identified by structural formulas set forth in the claims.

123. A patient who ingests a pharmaceutical product that contains sofosbuvir *necessarily* metabolizes sofosbuvir into compounds that satisfy the structural formulas set forth in the asserted claims of the '712 patent.

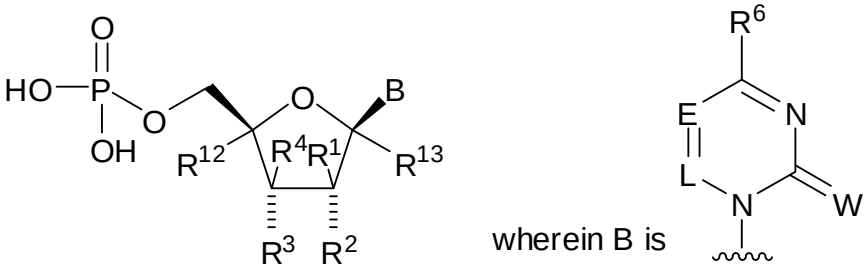
124. I understand the Court has adopted the following definitions of terms that appear in the claims of the '499 patent in an Order dated May 1, 2015:

> The term "in combination with" means "together with," whether given separately at different times during the course of therapy or concurrently in divided or single combination forms.
>
> The term "compound" means a substance that consists of two or more chemical elements in union.

125. I present my infringement analysis based on the meanings of these terms as set forth above. The results of my analysis are summarized in the claim chart that attached as Exhibit K to this Report. I reserve the right to revise or supplement my analysis based on positions provided in Plaintiff's expert reports.

A. Patients Who Take SOVALDI Infringe Claim 1 of the '712 Patent

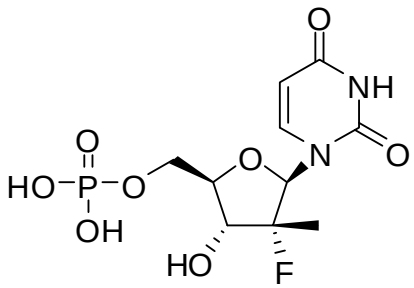
126. Claim 1 of the '712 patent is directed to monophosphate nucleotides that are defined by formula VIII, where the choices for W, E, L and R^x are specified in the claim.



Formula VIII

127. A patient who takes SOVALDI directly infringes claim 1 of the '712 patent by forming one or more compounds of formula VIII, as defined in that claim, through metabolism of sofosbuvir.

128. Sofosbuvir is metabolized in the body to form the following compound that falls within formula VIII of claim 1:



See Compound GS-606965 at GILEAD00084002; see also Compound PSI-7411, Murakami at 34344.

129. This compound falls within formula VIII of claim 1 in the following way: L = CH; E = CH; W = O; R^1 = CH_3 (C_{1-4} alkyl); R^2 = fluoro (halogen); R^3 = hydroxy; R^4 = H; R^6 = OH; R^{12} and R^{13} = H. This satisfies formula VIII where E = CR^5 and R^5 = H.

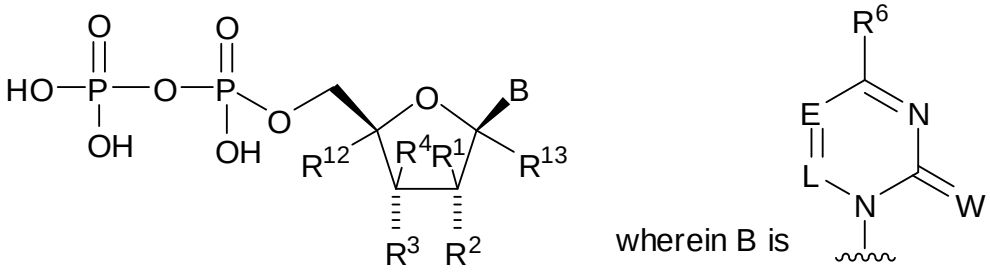
B. Gilead's Sale of SOVALDI with Directions for its Administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 1 of the '712 Patent

130. Gilead induces infringement of claim 1 of the '712 patent by selling SOVALDI with directions for its administration to treat HCV infection knowing that the resulting metabolism of sofosbuvir will result in formation of compounds of formula VIII that infringe claim 1 of the '712 patent.

131. Gilead contributes to infringement of claim 1 of the '712 patent because Gilead is aware that sofosbuvir metabolizes into compounds of formula VIII of claim 1 of the '712 patent, as shown by Gilead's scientific publications and submissions to the FDA, and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

C. Patients Who Take SOVALDI Infringe Claim 2 of the '712 Patent

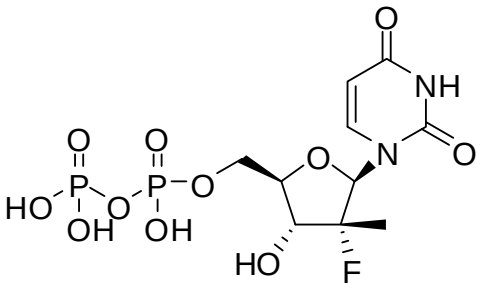
132. Claim 2 of the '712 patent is directed to diphosphate nucleotides that are defined by formula IX, where the choices for W, E, L and R^x are specified in the claim.



Formula IX

133. A patient who takes SOVALDI directly infringes claim 2 of the '712 patent by forming one or more of the compounds of formula IX, as defined in that claim, through metabolism of sofosbuvir.

134. Sofosbuvir is metabolized in the body to form the following compound that falls within formula IX of claim 2:



See Compound PSI-7410, Murakami at 34344, and the implied figure between the two kinase arrows at GILEAD00084002.

135. This compound falls within formula IX of claim 2 in the following way: L = CH; E = CH; W = O; R^1 = CH_3 (C_{1-4} alkyl); R^2 = fluoro (halogen); R^3 = hydroxy; R^4 = H; R^6 = OH; R^{12} and R^{13} = H. This satisfies formula IX where E = CR^5 and R^5 = H.

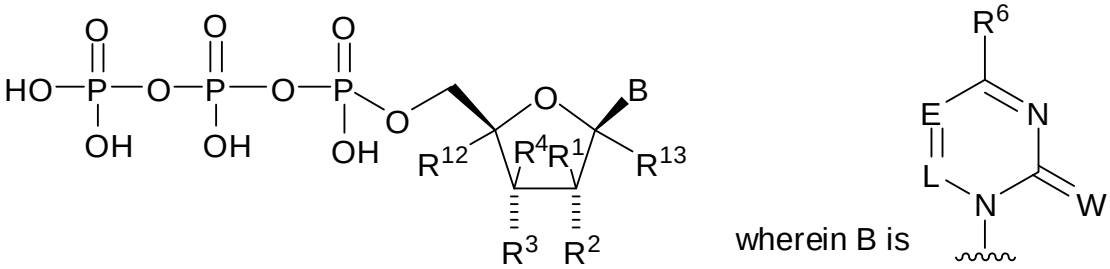
D. Gilead's Sale of SOVALDI with Directions for its Administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 2 of the '712 Patent

136. Gilead induces infringement of claim 2 of the '712 patent by selling SOVALDI with directions for its administration to treat HCV infection knowing that the resulting metabolism of sofosbuvir will result in formation of compounds of formula IX that infringe claim 2 of the '712 patent.

137. Gilead contributes to infringement of claim 2 of the '712 patent because Gilead is aware that sofosbuvir metabolizes into compounds of formula IX of claim 2 of the '712 patent, as shown by Gilead's scientific publications and submissions to the FDA, and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

E. Patients Who Take SOVALDI Infringe Claim 3 of the '712 Patent

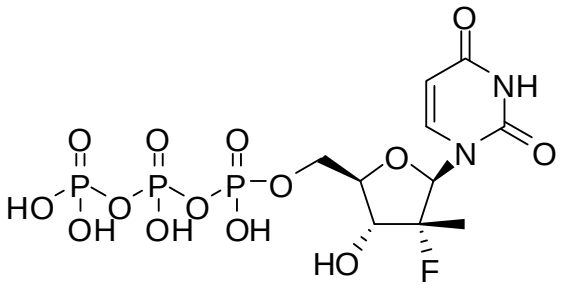
138. Claim 3 of the '712 patent is directed to triphosphate nucleotides that are defined by formula VII, where the choices for W, E, L and R^x are specified in the claim.



Formula VII

139. A patient who takes SOVALDI directly infringes claim 3 of the '712 patent by forming one or more of the compounds of formula VII, as defined in that claim, through metabolism of sofosbuvir.

140. Sofosbuvir is metabolized in the body to form the following compound that falls within formula VII of claim 3:



See Compound GS-461203 at GILEAD00084002; see also Compound PSI-7409, Murakami at 34344.

141. This compound falls within formula VII of claim 3 in the following way: L = CH; E = CH; W = O; R^1 = CH_3 (C_{1-4} alkyl); R^2 = fluoro (halogen); R^3 = hydroxy; R^4 = H; R^6 = OH; R^{12} and R^{13} = H. This satisfies formula VII where E = CR^5 and R^5 = H.

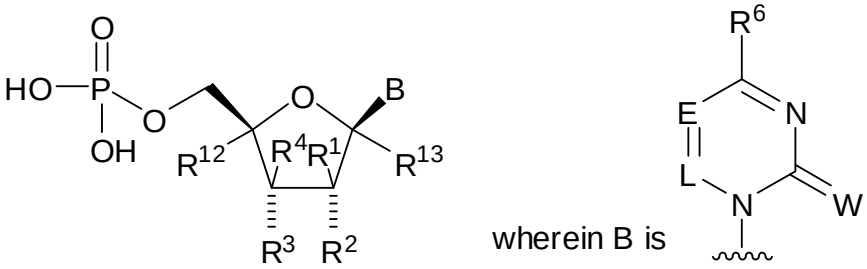
F. Gilead's Sale of SOVALDI with Directions for its Administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 3 of the '712 Patent

142. Gilead induces infringement of claim 3 of the '712 patent by selling SOVALDI with directions for its administration to treat HCV infection knowing that the resulting metabolism of sofosbuvir will result in formation of compounds of formula VII that infringe claim 3 of the '712 patent.

143. Gilead contributes to infringement of claim 3 of the '712 patent because Gilead's publications and submissions to the FDA acknowledge that sofosbuvir metabolizes into compounds of formula VII of claim 3 of the '712 patent and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

G. Patients Who Take SOVALDI Infringe Claim 5 of the '712 Patent

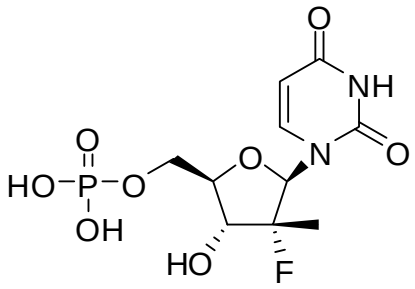
144. Claim 5 of the '712 patent is directed to monophosphate nucleotides that are defined by formula VIII, where the choices for W, E, L and R^x are specified in the claim.



Formula VIII

145. A patient who takes SOVALDI directly infringes claim 5 of the '712 patent by forming one or more of the compounds of formula VIII, as defined in that claim, through metabolism of sofosbuvir.

146. Sofosbuvir is metabolized in the body to form the following compound that falls within formula VIII of claim 5:



See Compound GS-606965 at GILEAD00084002; see also Compound PSI-7411, Murakami at 34344.

147. This compound falls within formula VIII of claim 5 in the following way: $R^1 = CH_3$ (C_{1-4} alkyl); R^2 = fluoro (halogen); R^3 = hydroxy; R^4 = H; R^{12} and R^{13} = H.

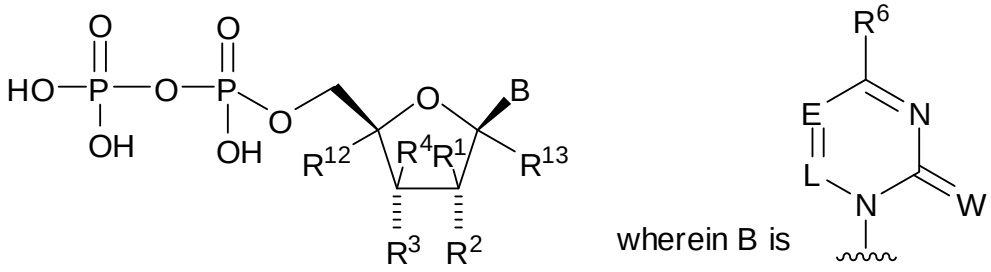
H. Gilead's Sale of SOVALDI with Directions for its Administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 5 of the '712 Patent

148. Gilead induces and contributes to infringement of claim 5 of the '712 patent by selling SOVALDI with directions for its administration to treat HCV infection knowing that the resulting metabolism of sofosbuvir will result in formation of compounds of formula VIII that infringe claim 5 of the '712 patent.

149. Gilead contributes to the infringement of claim 5 of the '712 patent because Gilead's publications and submissions to the FDA acknowledge that sofosbuvir metabolizes into compounds of formula VIII of claim 5 of the '712 patent and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

I. Patients Who Take SOVALDI Infringe Claim 7 of the '712 Patent

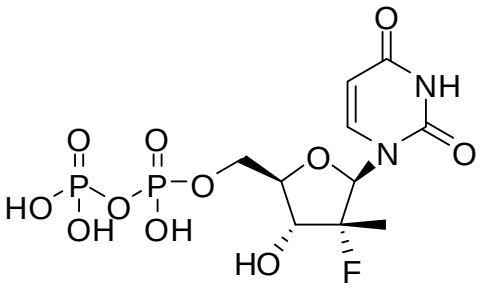
150. Claim 7 of the '712 patent is directed to diphosphate nucleotides that are defined by formula IX, where the choices for W, E, L and R^x are specified in the claim.



Formula IX

151. A patient who takes SOVALDI directly infringes claim 7 of the '712 patent by forming one or more of the compounds of formula IX, as defined in that claim, through metabolism of sofosbuvir.

152. Sofosbuvir is metabolized in the body to form the following compound that falls within formula IX of claim 7:



See Compound PSI-7410, at 34344, and the implied figure between the two kinase arrows at GILEAD00084002.

153. This compound falls within formula IX of claim 7 in the following way: $R^1 = CH_3$ (C_{1-4} alkyl); R^2 = fluoro (halogen); R^3 = hydroxy; R^4 = H; R^{12} and R^{13} = H.

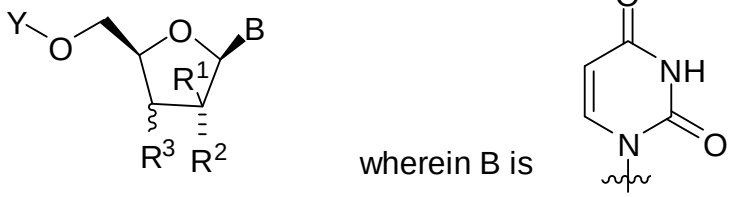
J. Gilead's Sale of SOVALDI with Directions for its Administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 7 of the '712 Patent

154. Gilead induces infringement of claim 7 of the '712 patent by selling SOVALDI with directions for its administration to treat HCV infection knowing that the resulting metabolism of sofosbuvir will result in formation of compounds of formula IX that infringe claim 7 of the '712 patent.

155. Gilead contributes to infringement of claim 7 of the '712 patent because Gilead's publications and submissions to the FDA acknowledge that sofosbuvir metabolizes into compounds of formula IX of claim 7 of the '712 patent and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

K. Patients Who Take SOVALDI Infringe Claim 9 of the '712 Patent

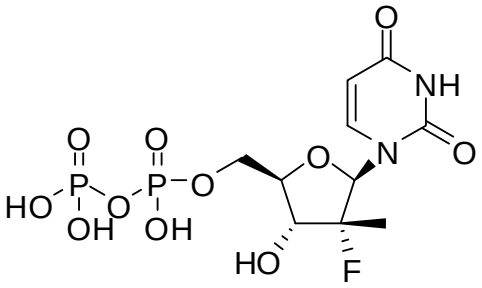
156. Claim 9 of the '712 patent is directed to di- and triphosphate nucleotides that are defined by formula III, where the choices for Y and R^x are specified in the claim.



Formula III

157. A patient who takes SOVALDI directly infringes claim 9 of the '712 patent by forming one or more of the compounds of formula III, as defined in that claim, through metabolism of sofosbuvir.

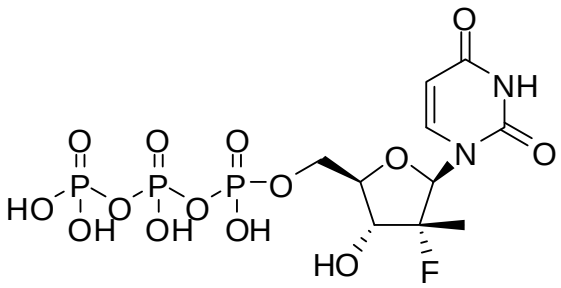
158. Sofosbuvir is metabolized in the body to form the following compound that falls within formula III of claim 9:



See Compound PSI-7410, Murakami at 34344, and the implied figure between the two kinase arrows at GILEAD00084002.

159. This compound falls within formula III of claim 9 in the following way: Y = $P_2O_6H_3$; R^1 = CH_3 (C_{1-4} alkyl); R^2 = fluoro; R^3 is OH.

160. Sofosbuvir is also metabolized in the body to form the following compound that falls within formula III of claim 9:



See Compound GS-461203 at GILEAD00084002; see also Compound PSI-7409, Murakami at 34344.

161. This compound falls within formula III of claim 9 in the following way: Y = $P_3O_9H_4$; R^1 = CH_3 (C_{1-4} alkyl); R^2 = fluoro; R^3 is OH.

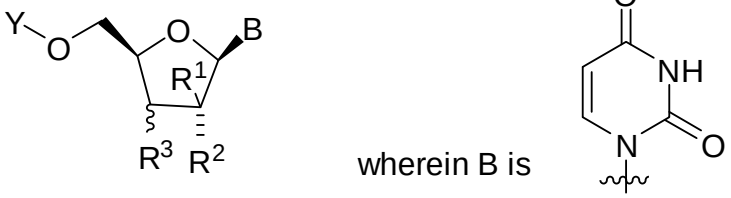
L. Gilead's Sale of SOVALDI with Directions for its Administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 9 of the '712 Patent

162. Gilead induces infringement of claim 9 of the '712 patent by selling SOVALDI with directions for its administration to treat HCV infection knowing that the resulting metabolism of sofosbuvir will result in formation of compounds of formula III that infringe claim 9 of the '712 patent.

163. Gilead contributes to infringement of claim 9 of the '712 patent because Gilead's publications and submissions to the FDA acknowledge that sofosbuvir metabolizes into compounds of formula III of claim 9 of the '712 patent and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

M. Patients Who Take SOVALDI Infringe Claim 10 of the '712 Patent

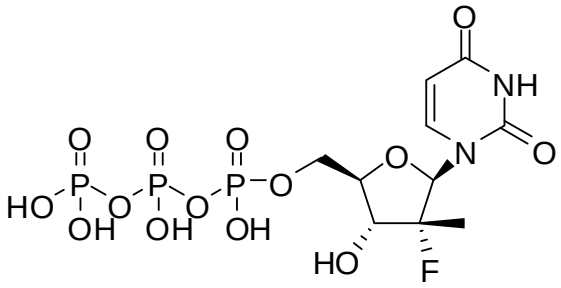
164. Claim 10 of the '712 patent is directed to triphosphate nucleotides that are defined by formula III, where the choices for Y and R^x are specified in the claim.



Formula III

165. A patient who takes SOVALDI directly infringes claim 10 of the '712 patent by forming one or more of the compounds of formula III, as defined in that claim, through metabolism of sofosbuvir.

166. Sofosbuvir is also metabolized in the body to form the following compound that falls within formula III of claim 10:



See Compound GS-461203 at GILEAD00084002; see also Compound PSI-7409, Murakami at 34344.

167. This compound falls within formula III in the following way: Y = $P_3O_9H_4$; R^1 = CH_3 (C_{1-4} alkyl); R^2 = fluoro; R^3 = OH of claim 10.

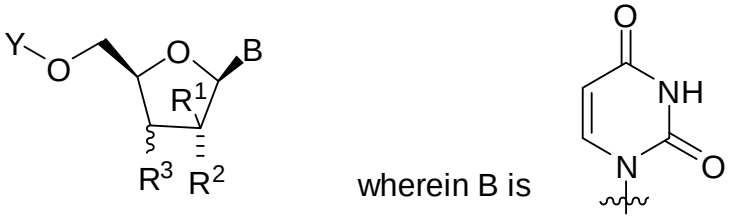
N. Gilead's Sale of SOVALDI with Directions for its Administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 10 of the '712 Patent

168. Gilead induces infringement of claim 10 of the '712 patent by selling SOVALDI with directions for its administration to treat HCV infection knowing that the resulting metabolism of sofosbuvir will result in formation of compounds of formula III that infringe claim 10 of the '712 patent.

169. Gilead contributes to infringement of claim 10 of the '712 patent because Gilead's publications and submissions to the FDA acknowledge that sofosbuvir metabolizes into compounds of formula III of claim 10 of the '712 patent and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

O. Patients Who Take SOVALDI Infringe Claim 11 of the '712 Patent

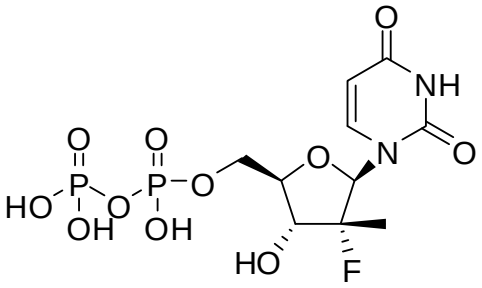
170. Claim 11 of the '712 patent is directed to diphosphate nucleotides that are defined by formula III, where the choices for Y and R^x are specified in the claim.



Formula III

171. A patient who takes SOVALDI directly infringes claim 11 of the '712 patent by forming one or more of the compounds of formula III, as defined in that claim, through metabolism of sofosbuvir.

172. Sofosbuvir is metabolized in the body to form the following compound that falls within formula III of claim 11:



See Compound PSI-7410, Murakami at 34344, and the implied figure between the two kinase arrows at GILEAD00084002.

173. This compound falls within formula III of claim 11 in the following way: Y = $P_2O_6H_3$; R^1 = CH_3 (C_{1-4} alkyl); R^2 = fluoro; R^3 = OH.

P. Gilead's Sale of SOVALDI with Directions for its Administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 11 of the '712 Patent

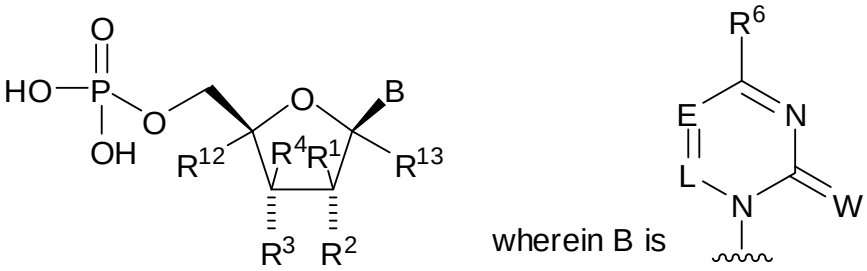
174. Gilead induces infringement of claim 11 of the '712 patent by selling SOVALDI with directions for its administration to treat HCV infection knowing that the resulting metabolism of

sofosbuvir will result in formation of compounds of formula III that infringe claim 11 of the '712 patent.

175. Gilead contributes to the infringement of claim 11 of the '712 patent because Gilead's publications and submissions to the FDA acknowledge that sofosbuvir metabolizes into compounds of formula III of claim 11 of the '712 patent and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

Q. Patients Who Take HARVONI Infringe Claim 1 of the '712 Patent

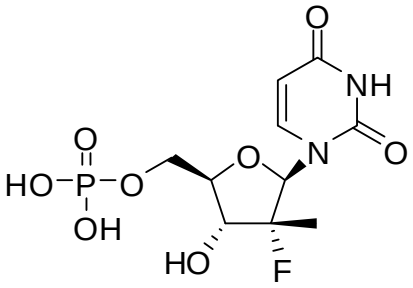
176. Claim 1 of the '712 patent is directed to monophosphate nucleotides that are defined by formula VIII, where the choices for W, E, L and R^x are specified in the claim.



Formula VIII

177. A patient who takes HARVONI directly infringes claim 1 of the '712 patent by forming one or more of the compounds of formula III, as defined in that claim, through metabolism of sofosbuvir.

178. Sofosbuvir is metabolized in the body to form the following compound that falls within formula VIII of claim 1:



See Compound GS-606965 at GILEAD00084002; see also Compound PSI-7411, Murakami at 34344.

179. This compound falls within formula VIII of claim 1 in the following way: L = CH; E = CH; W = O; $R^1 = CH_3$ (C_{1-4} alkyl); R^2 = fluoro (halogen); R^3 = hydroxy; R^4 = H; R^6 = OH; R^{12} and R^{13} = H. This satisfies formula VIII where E = CR^5 and R^5 = H.

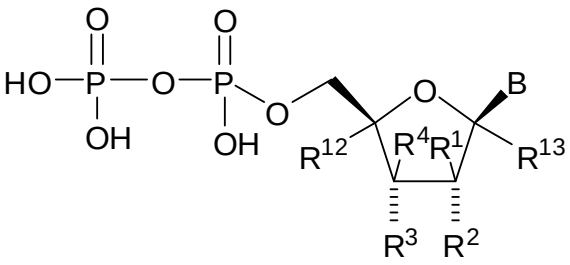
R. Gilead's Sale of HARVONI with Directions for its Administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 1 of the '712 Patent

180. Gilead induces infringement of claim 1 of the '712 patent by selling HARVONI with directions for its administration to treat HCV infection knowing that the resulting metabolism of sofosbuvir will result in formation of compounds of formula VIII that infringe claim 1 of the '712 patent.

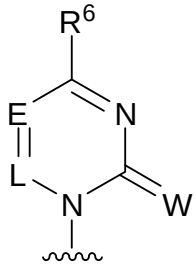
181. Gilead contributes to infringement of claim 1 of the '712 patent because Gilead's publications and submissions to the FDA acknowledge that sofosbuvir metabolizes into compounds of formula VIII of claim 1 of the '712 patent and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

S. Patients Who Take HARVONI Infringe Claim 2 of the '712 Patent

182. Claim 2 of the '712 patent is directed to diphosphate nucleotides that are defined by formula IX, where the choices for W, E, L and R^x are specified in the claim.



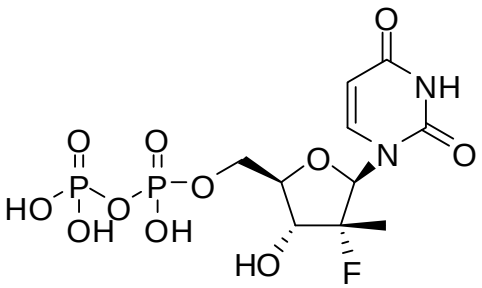
wherein B is



Formula IX

183. A patient who takes HARVONI directly infringes claim 2 of the '712 patent by forming one or more of the compounds of formula IX, as defined in that claim, through metabolism of sofosbuvir.

184. Sofosbuvir is metabolized in the body to form the following compound that falls within formula IX of claim 2:



See Compound PSI-7410, Murakami at 34344, and the implied figure between the two kinase arrows at GILEAD00084002.

185. This compound falls within formula IX of claim 2 in the following way: L = CH; E = CH; W = O; R^1 = CH_3 (C_{1-4} alkyl); R^2 = fluoro (halogen); R^3 = hydroxy; R^4 = H; R^6 = OH; R^{12} and R^{13} = H. This satisfies formula IX where E = CR^5 and R^5 = H.

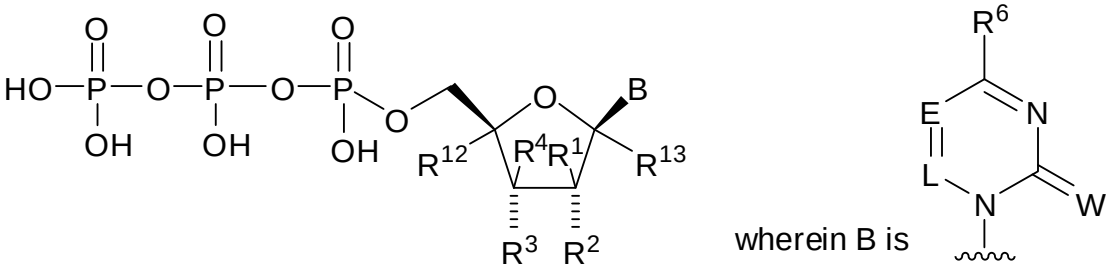
T. Gilead's Sale of HARVONI with directions for its administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 2 of the '712 Patent

186. Gilead induces infringement of claim 2 of the '712 patent by selling HARVONI with directions for its administration to treat HCV infection knowing that the resulting metabolism of sofosbuvir will result in formation of compounds of formula IX that infringe claim 2 of the '712 patent.

187. Gilead contributes to infringement of claim 2 of the '712 patent because Gilead's publications and submissions to the FDA acknowledge that sofosbuvir metabolizes into compounds of formula IX of claim 2 of the '712 patent and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

U. Patients Who Take HARVONI Infringe Claim 3 of the '712 Patent

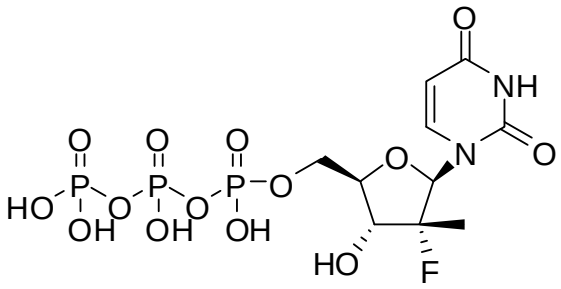
188. Claim 3 of the '712 patent describes triphosphate nucleotides as described in formula VII, where the choices for W, E, L and R^x are specified in the claim.



Formula VII

189. A patient who takes HARVONI directly infringes claim 3 of the '712 patent by forming one or more of the compounds of formula VII, as defined in that claim, through metabolism of sofosbuvir.

190. Sofosbuvir is metabolized in the body to form the following compound that falls within formula VII of claim 3:



See Compound GS-461203 at GILEAD00084002; see also Compound PSI-7409, Murakami at 34344.

191. This compound falls within formula VII of claim 3 in the following way: L = CH; E = CH; W = O; R^1 = CH_3 ($C_{1\text{-}4}$ alkyl); R^2 = fluoro (halogen); R^3 = hydroxy; R^4 = H; R^6 = OH; R^{12} and R^{13} = H. This satisfies formula VII where E = CR^5 and R^5 = H.

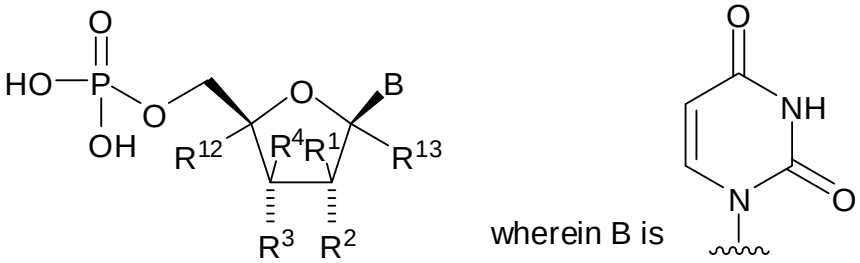
V. Gilead's Sale of HARVONI with Directions for its administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 3 of the '712 Patent

192. Gilead induces infringement of claim 3 of the '712 patent by selling HARVONI with directions for its administration to treat HCV infection knowing that the resulting metabolism of sofosbuvir will result in formation of compounds of formula VII that infringe claim 3 of the '712 patent.

193. Gilead contributes to infringement of claim 3 of the '712 patent because Gilead's publications and submissions to the FDA acknowledge that sofosbuvir metabolizes into compounds of formula VII of claim 3 of the '712 patent and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

W. Patients Who Take HARVONI Infringe Claim 5 of the '712 Patent

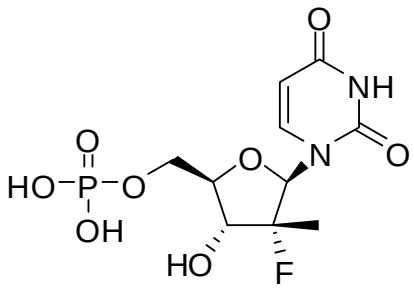
194. Claim 5 of the '712 patent is directed to monophosphate nucleotides that are defined by formula VIII, where the choices for R^x are specified in the claim.



Formula VIII

195. A patient who takes HARVONI directly infringes claim 5 of the '712 patent by forming one or more of the compounds of formula VIII, as defined in that claim, through metabolism of sofosbuvir.

196. Sofosbuvir is metabolized in the body to form the following compound that falls within formula VIII of claim 5:



See Compound GS-606965 at GILEAD00084002; see also Compound PSI-7411, Murakami at 34344.

197. This compound falls within formula VIII of claim 5 in the following way: $R^1 = CH_3$ (C_{1-4} alkyl); R^2 = fluoro (halogen); R^3 = hydroxy; R^4 = H; R^{12} and R^{13} = H.

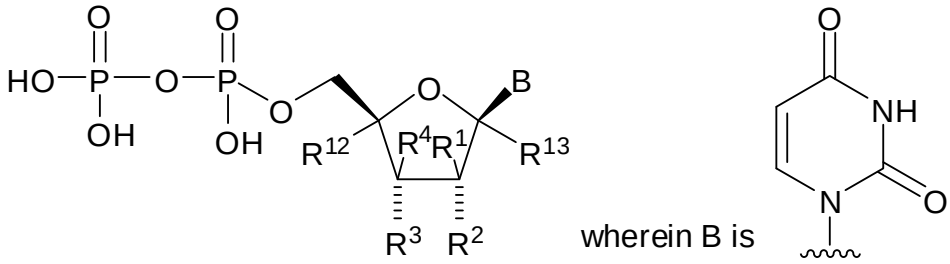
X. Gilead's Sale of HARVONI with Directions for its Administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 5 of the '712 Patent

198. Gilead induces infringement of claim 5 of the '712 patent by selling HARVONI with directions for its administration to treat HCV infection knowing that the resulting metabolism of sofosbuvir will result in formation of compounds of formula VIII that infringe claim 5 of the '712 patent.

199. Gilead contributes to infringement of claim 5 of the '712 patent because Gilead's publications and submissions to the FDA acknowledge that sofosbuvir metabolizes into compounds of formula VIII of claim 5 of the '712 patent and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

Y. Patients Who Take HARVONI Infringe Claim 7 of the '712 Patent

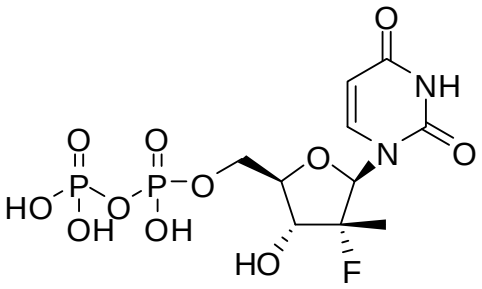
200. Claim 7 of the '712 patent describes diphosphate nucleotides as described in formula IX, where the choices for R^x are specified in the claim.



Formula IX

201. A patient who takes HARVONI directly infringes claim 7 of the '712 patent by forming one or more of the compounds of formula IX, as defined in that claim, through metabolism of sofosbuvir.

202. Sofosbuvir is metabolized in the body to form the following compound that falls within formula IX of claim 7:



See Compound PSI-7410, Murakami at 34344, and the implied figure between the two kinase arrows at GILEAD00084002.

203. This compound falls within formula IX of claim 7 in the following way: $R^1 = CH_3$ (C_{1-4} alkyl); R^2 = fluoro (halogen); R^3 = hydroxy; R^4 = H; R^{12} and R^{13} = H.

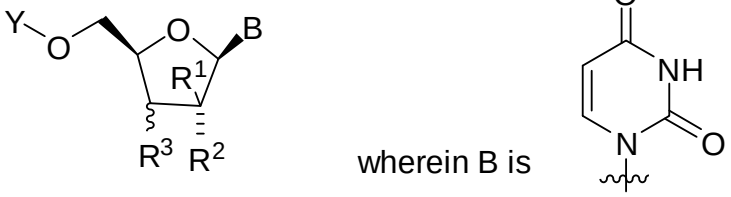
Z. Gilead's Sale of HARVONI with Directions for its Administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 7 of the '712 Patent

204. Gilead induces infringement of claim 7 of the '712 patent by selling HARVONI with directions for its administration to treat HCV infection knowing that the resulting metabolism of sofosbuvir will result in formation of compounds of formula IX that infringe claim 7 of the '712 patent.

205. Gilead contributes to infringement of claim 7 of the '712 patent because Gilead's publications and submissions to the FDA acknowledge that sofosbuvir metabolizes into compounds of formula IX of claim 7 of the '712 patent and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

AA. Patients Who Take HARVONI Infringe Claim 9 of the '712 Patent

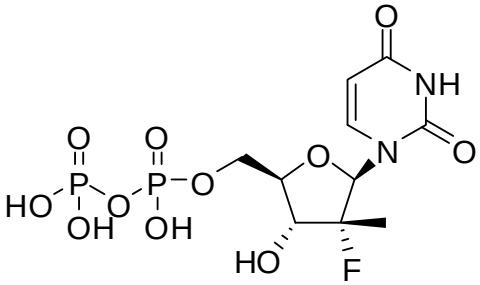
206. Claim 9 of the '712 patent is directed to di- and triphosphate nucleotides that are defined by formula III, where the choices for Y and R^x are specified in the claim.



Formula III

207. A patient who takes HARVONI directly infringes claim 9 of the '712 patent by forming one or more of the compounds of formula III, as defined in that claim, through metabolism of sofosbuvir.

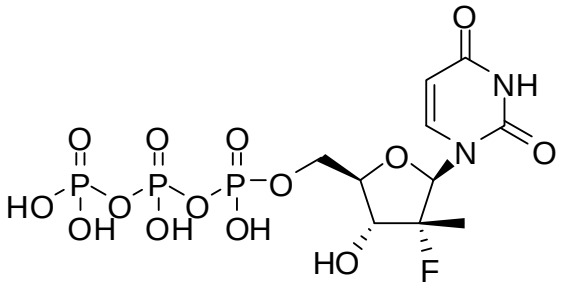
208. Sofosbuvir is metabolized in the body to form the following compound that falls within formula III of claim 9:



See Compound PSI-7410, Murakami at 34344, and the implied figure between the two kinase arrows at GILEAD00084002.

209. This compound falls within formula III of claim 9 in the following way: Y = $P_2O_6H_3$; R^1 = CH_3 ($C_{1\text{-}4}$ alkyl); R^2 = fluoro; R^3 is OH.

210. Sofosbuvir is also metabolized in the body to form the following compound that falls within formula III of claim 9:



See Compound GS-461203 at GILEAD00084002; see also Compound PSI-7409, Murakami at 34344.

211. This compound falls within formula III of claim 9 in the following way: Y = $P_3O_9H_4$; R^1 = CH_3 (C_{1-4} alkyl); R^2 = fluoro; R^3 = OH.

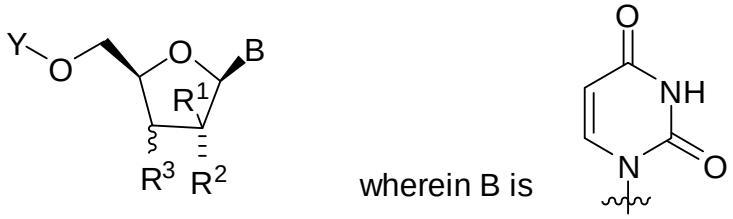
BB. Gilead's Sale of HARVONI with Directions for its Administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 9 of the '712 Patent

212. Gilead induces infringement of claim 9 of the '712 patent by selling HARVONI with directions for its administration to treat HCV infection knowing that the resulting metabolism of sofosbuvir will result in formation of compounds of formula III that infringe claim 9 of the '712 patent.

213. Gilead contributes to infringement of claim 9 of the '712 patent because Gilead's publications and submissions to the FDA acknowledge that sofosbuvir metabolizes into compounds of formula III of claim 9 of the '712 patent and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

CC. Patients Who Take HARVONI Infringe Claim 10 of the '712 Patent

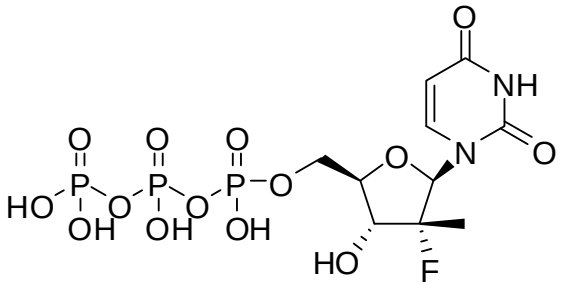
214. Claim 10 of the '712 patent is directed to triphosphate nucleotides that are defined by formula III, where the choices for Y and R^x are specified in the claim.



Formula III

215. A patient who takes HARVONI directly infringes claim 10 of the '712 patent by forming one or more of the compounds of formula III, as defined in that claim, through metabolism of sofosbuvir.

216. Sofosbuvir is metabolized in the body to form the following compound that falls within formula III of claim 10:



See Compound GS-461203 at GILEAD00084002; see also Compound PSI-7409, Murakami at 34344.

217. This compound falls within formula III of claim 10 in the following way: Y = $P_3O_9H_4$; R^1 = CH_3 (C_{1-4} alkyl); R^2 = fluoro; R^3 = OH.

DD. Gilead's Sale of HARVONI with Directions for its Administration to Treat HCV Infection I8nduces and Contributes to Infringement of Claim 10 of the '712 Patent

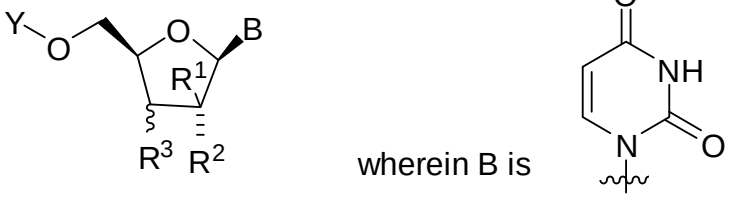
218. Gilead induces infringement of claim 10 of the '712 patent by selling HARVONI with directions for its administration to treat HCV infection knowing that the resulting metabolism of

sofosbuvir will result in formation of compounds of formula III that infringe claim 10 of the '712 patent.

219. Gilead contributes to infringement of claim 10 of the '712 patent because Gilead's publications and submissions to the FDA acknowledge that sofosbuvir metabolizes into compounds of formula III of claim 10 of the '712 patent and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

EE. Patients Who Take HARVONI Infringe Claim 11 of the '712 Patent

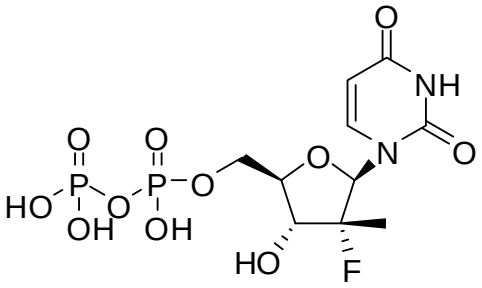
220. Claim 11 of the '712 patent is directed to diphosphate nucleotides that are defined by formula III, where the choices for Y and R^x are specified in the claim.



Formula III

221. A patient who takes HARVONI directly infringes claim 11 of the '712 patent by forming one or more of the compounds of formula III, as defined in that claim, through metabolism of sofosbuvir.

222. Sofosbuvir is metabolized in the body to form the following compound that falls within formula III of claim 11:



See Compound PSI-7410, Murakami at 34344, and the implied figure between the two kinase arrows at GILEAD00084002.

223. This compound falls within formula III of claim 11 in the following way: Y = $P_2O_6H_3$; R^1 = CH_3 (C_{1-4} alkyl); R^2 = fluoro; R^3 = OH.

FF. Gilead's Sale of HARVONI with Directions for its Administration to Treat HCV Infection Induces and Contributes to Infringement of Claim 11 of the '712 Patent

224. Gilead induces infringement of claim 11 of the '712 patent by selling HARVONI with directions for its administration to treat HCV infection knowing that the resulting metabolism of sofosbuvir will result in formation of compounds of formula III that infringe claim 11 of the '712 patent.

225. Gilead contributes to infringement of claim 11 of the '712 patent because Gilead's publications and submissions to the FDA acknowledge that sofosbuvir metabolizes into compounds of formula III of claim 11 of the '712 patent and there is no FDA-approved use for SOVALDI that does not result in formation of those compounds.

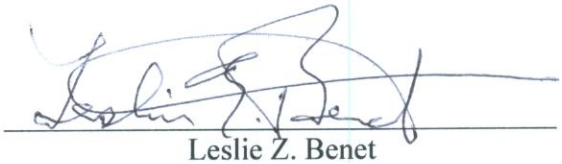
XI. Right To Supplement Or Amend

226. This report is based on information currently available to me. I reserve the right to supplement and/or amend the opinions expressed in this report in response to positions taken by plaintiff or experts retained on their behalf or new information presented by plaintiff's experts prior to, or at, trial.

227. The documents I specifically reference in this report are exemplary and are intended to aid understanding. If called upon, I may further testify as to facts, opinions and other matters relevant to this action. In this regard, I reserve the right to supplement my report as necessary to address any such additional matters. I reserve the right to rely upon other materials generated in further discovery proceedings or presented at trial. In connection with my testimony, I may also use certain graphic and/or demonstrative materials to illustrate my testimony at trial. I reserve the right to rely upon testimony or other materials generated in further discovery proceedings or presented at trial.

228. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct, to the best of my knowledge and belief.

Executed on: July 17, 2015



Leslie Z. Benet

66088025

CERTIFICATE OF SERVICE

I certify that all counsel of record are being served on October 29, 2015 with a copy of this document via the Court's CM/ECF system.

/s/ Stephen S. Rabinowitz
STEPHEN S. RABINOWITZ